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<p>(21) International Application Number: PCT/US92/02829            (22) International Filing Date: 7 April 1992 (07.04.92)</p> <p>(30) Priority data:            685,130 12 April 1991 (12.04.91) US            856,514 24 March 1992 (24.03.92) US</p> <p>(71) Applicant: INCONTROL, INC. [US/US]; 6675 185th Avenue, N.E., Suite 100, Redmond, WA 98052 (US).</p> <p>(72) Inventors: ADAMS, John, M. ; 4704 19th Avenue, S.E., Issaquah, WA 98027 (US). ALFERNESS, Clifton, A. ; 2022 235th Place, Redmond, WA 98053 (US). KREYENHAGEN, Paul, E. ; 15214 N.E. 8th Street, Apt. G10, Bellevue, WA 98007 (US).</p>		<p>(74) Agents: O'SHAUGHNESSY, James, P. et al.; Foley &amp; Lardner, 777 East Wisconsin Avenue, Milwaukee, WI 53202-5367 (US).</p> <p>(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), SE (European patent).</p> <p>Published  <i>Without international search report and to be republished upon receipt of that report.</i></p>	
<p><b>(54) Title: IMPROVED ATRIAL DEFIBRILLATOR, LEAD SYSTEMS, AND METHOD</b></p> <p><b>(57) Abstract</b></p> <p>An implantable atrial defibrillator provides a pulse of defibrillating electrical energy to the atria of the heart in synchronism with sensed R waves in response to non-coincident sensing of an R wave at first and second areas of the heart. The defibrillating pulse is provided after a predetermined number of consecutive R waves are non-coincidentally sensed to assure reliable synchronization. The atrial defibrillator is also operational in a marker mode wherein a number of synchronization marker pulses are delivered to the heart for detection on an externally generated electrocardiogram. The atrial fibrillation detector of the defibrillator is normally disabled and is activated when the sensed ventricular activity indicates a probability of atrial fibrillation to conserve a depletable power source. A plurality of lead systems are also described for use with the atrial defibrillator which reduce the quantity of electrical energy required to defibrillate the heart and ensure that the delivered atrial defibrillating electrical energy is substantially confined to the atria of the heart.</p>			

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**IMPROVED ATRIAL DEFIBRILLATOR,  
LEAD SYSTEMS, AND METHOD**

**REFERENCE TO CO-PENDING APPLICATION**

This is a continuation-in-part of application  
Serial No. 07/685,130, filed April 12, 1991, for IMPROVED  
5 ATRIAL DEFIBRILLATOR AND METHOD.

**BACKGROUND OF THE INVENTION**

The present invention generally relates to an  
atrial defibrillator for delivering a pulse of  
10 defibrillating electrical energy to the atria of a human  
heart. The present invention is more particularly  
directed to a fully automatic implantable atrial  
defibrillator which exhibits reduced power consumption,  
reliable synchronized delivery of defibrillating  
15 electrical energy to the atria, and multiple modes of  
operation including bradycardia pacing. The present  
invention is further directed to an improved endocardial  
lead for delivering the defibrillating electrical energy  
20 to the atria while minimizing the electrical energy  
applied to the ventricles. The present invention is still  
further directed to lead systems for use in an atrial  
defibrillator and method for monitoring activity of the  
heart and delivering cardioverting or defibrillating  
25 electrical energy to the heart.

25 Atrial fibrillation is probably the most common  
cardiac arrhythmia. Although it is not usually a life  
threatening arrhythmia, it is associated with strokes  
thought to be caused by blood clots forming in areas of  
stagnant blood flow as a result of prolonged atrial  
30 fibrillation. In addition, patients afflicted with atrial  
fibrillation generally experience palpitations of the  
heart and may even experience dizziness or even loss of  
consciousness.

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5 Atrial fibrillation occurs suddenly and many times can only be corrected by a discharge of electrical energy to the heart through the skin of the patient by way of an external defibrillator of the type well known in the art. This treatment is commonly referred to as synchronized cardioversion and, as its name implies, involves applying electrical defibrillating energy to the heart in synchronism with a detected electrical activation (R wave) of the heart. The treatment is very painful and, 10 unfortunately, most often only results in temporary relief for patients, lasting but a few weeks.

15 Drugs are available for reducing the incidence of atrial fibrillation. However, these drugs have many side effects and many patients are resistant to them which greatly reduces their therapeutic effect.

20 Implantable atrial defibrillators have been proposed to provide patients suffering from occurrences of atrial fibrillation with relief. Unfortunately, to the detriment of such patients, none of these atrial defibrillators have become a commercial reality.

25 Implantable atrial defibrillators proposed in the past have exhibited a number of disadvantages which probably has been the cause of these defibrillators from becoming a commercial reality. Two such defibrillators, although represented as being implantable, were not fully automatic, requiring human interaction for cardioverting or defibrillating the heart. Both of these defibrillators require the patient to recognize the symptoms of atrial fibrillation with one defibrillator requiring a visit to 30 a physician to activate the defibrillator and the other defibrillator requiring the patient to activate the defibrillator from external to the patient's skin with a magnet.

35 Synchronizing the delivery of the defibrillating or cardioverting energy with an electrical activation (R wave) of the heart is important to prevent ventricular fibrillation. Ventricular fibrillation is a fatal arrhythmia which can be caused by electrical energy being

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delivered to the heart at the wrong time in the cardiac cycle, such as during the T wave of the cycle. As a result, it is most desirable to sense electrical activations of the heart to generate synchronization 5 pulses (or signals) in a manner which avoids detecting noise as an electrical activation. Unfortunately, implantable atrial defibrillators proposed to date have not provided either such noise immunity or any other means for assuring reliable synchronization.

10 Another measure for reducing the risk of inducing ventricular fibrillation during the delivery of defibrillating electrical energy to the atria of the heart is to reduce the amount of the electrical energy which is passed through the ventricles. In other words, it is 15 advantageous to confine the electrical energy to the atria as much as possible.

Implantable defibrillators, in general, must be powered by a portable, depletable power sources, such as a battery. However, an automatic implantable atrial 20 defibrillator which continuously monitors atrial activity of the heart and which continuously monitors for atrial fibrillation will consume so much power that frequent battery replacement, requiring explanting the defibrillator, would be necessary.

25 The atrial defibrillator of the present invention provides solutions to all of the above noted deficiencies in atrial defibrillators proposed to date and other features which obviate potential problems in implantable atrial defibrillators. In general, the atrial 30 defibrillator of the present invention is fully automatic and provides reliable synchronization to electrical activations, both through noise immune electrical activation sensing and through a test mode which permits a physician to confirm reliable electrical activation 35 sensing. The atrial defibrillator of the present invention also provides for conserving battery power by activating the atrial fibrillation detector only when the ventricular rate indicates a probability of atrial

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fibrillation. In addition, the atrial defibrillator of the present invention provides a new and improved endocardial lead and a method for using the same which assures that the delivered electrical energy is confined 5 to the atria and little of the electrical energy is passed through the ventricles.

In addition to the foregoing, the lead systems and method disclosed herein reduce battery power consumption and hence lengthen the useful life of an 10 implanted atrial defibrillator employing such lead systems. The lead systems disclosed herein are configured for placing the cardioverting or defibrillating electrodes in the heart at locations which minimize the energy which must be delivered to the atria for cardioverting or 15 defibrillating the same. Furthermore, the cardioverting or defibrillating energy levels disclosed herein are intended to provide a fifty percent probability of successful defibrillation or cardioversion. This is based upon the recognition that atrial fibrillation is not 20 generally life threatening and that if a second delivery of cardioverting or defibrillating electrical energy is required for successful cardioversion or defibrillation, the life of the patient will not be threatened. The end 25 result is less battery power consumption, extended life of the atrial defibrillator, and of greatest importance, less frequent surgical replacement of the atrial defibrillator to provide the patient with greater comfort and less risk commonly attendant to all surgeries.

30

SUMMARY OF THE INVENTION

The present invention provides an atrial defibrillator for applying an electrical defibrillating pulse to the atria of a human heart, wherein the atrial defibrillator is arranged to apply the electrical defibrillating pulse to the atria in synchronism with 35 depolarization activation waves, and includes first means for sensing depolarization activation waves at a first area of the heart and second means for sensing the

depolarization activation waves at a second area of the heart. The atrial defibrillator further includes means for detecting non-coincident sensing of a depolarization activation wave at the first area of the heart by the 5 first means and at the second area of the heart by the second means, storage means for storing electrical energy, and delivery means coupled to the storage means and being responsive to the non-coincident sensing of a depolarization activation wave at the first and second 10 areas of the heart for applying a predetermined amount of the stored electrical energy to the atria.

The present invention further provides an implantable atrial cardioverter arranged to be powered by a depletable power source for delivering electrical energy 15 to the atria of a human heart in need of cardioversion. The atrial cardioverter includes sensing means for sensing electrical activations of the heart, wherein the sensing means is continuously operable, means responsive to the sensing means for determining the time intervals between 20 the sensed electrical activations, and atrial arrhythmia detector means for detecting the presence of an atrial arrhythmia of the heart. The atrial arrhythmia detecting means is normally disabled to avoid excessive consumption of the depletable power source. The atrial cardioverter 25 further includes enable means for enabling the atrial arrhythmia detector means responsive to the determined time intervals and delivery means responsive to the atrial arrhythmia detector means for delivering the electrical energy to the atria of the heart in response to the atrial arrhythmia 30 detector means detecting an atrial arrhythmia of the heart.

The present invention further provides an atrial defibrillator arranged to be implanted beneath the skin of a patient for applying electrical energy to the atria of 35 a human heart. The atrial defibrillator includes sensing means for sensing electrical activations of the heart, first delivery means for delivering a first quantity of electrical energy to the atria of the heart in synchronism

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with one of the sensed electrical activations for cardioverting the heart, second delivery means for delivering at least one pulse of electrical energy to the heart in synchronism with one of the sensed electrical activations, wherein the pulse of electrical energy is of insufficient quantity to cardiovert the heart so as to be detected on an electrocardiogram generated externally to the skin of the patient, and select means for selecting either the first delivery means or the second delivery means.

The present invention further provides an atrial defibrillator for applying an electrical defibrillating pulse to the atria of a human heart in synchronism with an electrical activation of the heart. The atrial defibrillator includes sensing means for sensing electrical activations of the heart, synchronizing pulse generating means responsive to the sensing means for generating a synchronizing pulse for each sensed electrical activation, and counting means for counting the synchronizing pulses provided by the synchronizing pulse generating means. The atrial defibrillator also includes delivery means responsive to the counting means for applying the electrical defibrillating pulse to the atria after a predetermined number of the synchronizing pulses have been counted by the counter means and in response to the last one of the predetermined number of synchronizing pulses.

The present invention further provides an intravascular lead for use in association with an atrial defibrillator of the type arranged to cardiovert the atria of the human heart. The lead includes a distal end and a proximal end, the proximal end including connector means arranged to be received by the atrial defibrillator, and wherein the connector means includes first, second, and third contacts. The lead further includes a first electrode at the distal end, a second electrode proximal to the first electrode, and a third electrode proximal to the second electrode. The lead further includes conductor

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means for electrically connecting the first contact to the first electrode, the second contact to the second electrode, and the third contact to the third electrode and the lead being flexible so as to be arranged to be  
5 passed down the superior vena cava of the heart, into the right atrium, into the coronary sinus ostium, and advanced into the coronary sinus of the heart near the left side thereof. The electrodes are spaced apart such that when the first electrode is within the coronary sinus adjacent  
10 the left ventricle, the second electrode is beneath the left atrium near the left ventricle and the third electrode is within the right atrium or the superior vena cava.

The present invention further provides an  
15 implantable atrial defibrillator for applying an electrical defibrillating pulse to the atria of a human heart. The atrial defibrillator includes first means for sensing electrical activations of the heart at the right ventricle, second means for sensing electrical activations  
20 of the heart at the left ventricle, and enable means responsive to the first means for detecting an abnormal rhythm of the right ventricle and providing an enable control signal. The atrial defibrillator further includes atrial fibrillation detector means including atrial  
25 sensing means for sensing atrial activity of at least one of the atria, the atrial fibrillation detector means being arranged to be activated by the enable control signal for detecting atrial fibrillation of the heart, and storage means for storing the electrical energy responsive to the  
30 atrial fibrillation detector means detecting atrial fibrillation. The atrial defibrillator further includes delivery means responsive to the atrial fibrillation detector means, coupled to the storage means, and being responsive to non-coincident sensing of an electrical activation by said first and second means for applying a predetermined amount of the stored electrical energy to  
35 the atria of the heart.

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The present invention further provides a method of applying electrical defibrillating energy to the atria of a human heart while minimizing the electrical energy applied to the right and left ventricles. The method 5 includes the steps of providing a first electrode, establishing electrical contact between the first electrode and point within the coronary sinus beneath the left atrium, providing a second electrode, establishing electrical contact between the second electrode and a 10 region adjacent to the right atrium, and applying defibrillating electrical energy between the first and second electrodes.

The present invention still further provides a lead system for use with an implantable device for 15 monitoring activity of the heart and delivering cardioverting electrical energy to the atria of the heart wherein the device includes storage means for storing the electrical energy. The lead system includes lead means coupled to the storage means for receiving the electrical 20 energy from the storage means. The lead means applies the electrical energy between the right atrium of the heart and at least one of the coronary sinus beneath the left atrium of the heart and the left pulmonary artery adjacent the left atrium of the heart for delivering the electrical 25 energy to the atria of the heart. The lead means is fully implantable beneath the skin of a patient.

The present invention still further provides a method of monitoring activity of the heart of a patient and delivering cardioverting electrical energy to the 30 atria of the heart of the patient. The method includes the steps of providing storage means for storing electrical energy, implanting the storage means beneath the skin of the patient, providing lead means, and implanting the lead means beneath the skin of the patient. 35 The method further includes the steps of coupling the lead means to the storage means, storing the electrical energy in the storage means, and applying, through the lead means, at least a portion of the stored electrical energy

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between the right atrium of the heart and at least one of the coronary sinus beneath the left atrium of the heart and the left pulmonary artery adjacent the left atrium of the heart to deliver the cardioverting electrical energy 5 to the atria of the heart.

BRIEF DESCRIPTION OF THE DRAWINGS

The features of the present invention which are believed to be novel are set forth with particularity in 10 the appended claims. The invention, together with further objects and advantages thereof, may best be understood by making reference to the following description taken in conjunction with the accompanying drawing, in the several figures of which like reference numerals identify 15 identical elements, and wherein:

Figure 1 is a schematic block diagram of a fully implantable atrial defibrillator embodying the present invention for applying defibrillating electrical energy to the atria of a human heart and which is shown in 20 association with a human heart in need of atrial fibrillation monitoring and potential cardioversion of the atria;

Figure 2 is a flow diagram illustrating the manner in which the atrial defibrillator of Figure 1 may 25 be implemented in accordance with the present invention for providing bradycardia pacing of the right ventricle of the heart and for determining and storing the time intervals between depolarizations of the right ventricle;

Figure 3 is a flow diagram illustrating the manner in which the atrial defibrillator of Figure 1 may 30 be implemented in accordance with the present invention for enabling the atrial fibrillation detector of the atrial defibrillator;

Figure 4 is a flow diagram illustrating the manner in which the atrial defibrillator of Figure 1 may 35 be implemented in accordance with the present invention for detecting atrial fibrillation and enabling either the

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atrial defibrillating output or the right ventricle marker pulse output;

5 Figure 5 is a flow diagram illustrating the manner in which the atrial defibrillator of Figure 1 may be implemented in accordance with the present invention for providing right ventricle marker pulses in synchronism with detected electrical activations (R waves) of the heart;

10 Figure 6 is a flow diagram illustrating the manner in which the atrial defibrillator of Figure 1 may be implemented in accordance with the present invention for providing defibrillating electrical energy to the atria of the heart in synchronism with detected electrical activations (R waves) of the heart;

15 Figure 7 is a top plan view illustrating an endocardial lead embodying the present invention having a plurality of electrodes for sensing electrical activations of the left ventricle, sensing electrical activations of the atria, and applying defibrillating electrical energy 20 to the atria;

Figure 8 is a cross-sectional view, to an enlarged scale, taken along lines 8-8 of Figure 7;

25 Figure 9 is a perspective view of the human heart having a lead system configured in accordance with a first lead system preferred embodiment of the present invention implanted therein;

30 Figure 10 is a perspective view of the human heart having a lead system configured in accordance with a second lead system preferred embodiment of the present invention implanted therein;

Figure 11 is a perspective view of the human heart having a lead system configured in accordance with a third lead system preferred embodiment of the present invention implanted therein;

35 Figure 12 is a perspective view of the human heart having a lead system configured in accordance with a fourth lead system preferred embodiment of the present invention implanted therein;

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Figure 13 is a perspective view of the human heart, with selected portions thereof broken away, having a lead system configured in accordance with a fifth lead system preferred embodiment of the present invention 5 implanted therein;

Figure 14 is a perspective view of the human heart having a lead system configured in accordance with a sixth lead system preferred embodiment of the present invention implanted therein;

10 Figure 15 is a perspective view of the human heart, with selected portions thereof broken away, having a lead system configured in accordance with a seventh lead system preferred embodiment of the present invention implanted therein; and

15 Figure 16 is a perspective view of the human heart having a lead system configured in accordance with an eighth lead system preferred embodiment of the present invention implanted therein.

20 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to Figure 1, it illustrates a fully implantable atrial defibrillator 30 embodying the present invention shown in association with a schematically illustrated human heart 10 in need of atrial fibrillation monitoring and potential cardioversion of the atria. The portions of the heart 10 illustrated in Figure 1 are the right ventricle 12, the left ventricle 14, the right atrium 16, the left atrium 18, the superior vena cava 20, the coronary sinus 22, the coronary sinus ostium 25 or opening 24, the left ventricular free wall 26 and the inferior vena cava 27. In addition, as used herein, the term "electrical activations" denotes R waves of the heart 30 cardiac cycle which induce depolarizations of the ventricles 12 and 14.

35 The atrial defibrillator 30 generally includes an enclosure 32 for hermetically sealing the internal circuit elements of the atrial defibrillator to be described hereinafter, an endocardial first lead 34, and

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an intravascular second lead 36. The enclosure 32 and first and second leads 34 and 36 are arranged to be implanted beneath the skin of a patient so as to render the atrial defibrillator 30 fully implantable.

5        The endocardial first lead 34 preferably comprises a endocardial bi-polar lead having electrodes 38 and 40 arranged for establishing electrical contact with the right ventricle 12 of the heart 10. The electrodes 38 and 40 permit bi-polar sensing of electrical activations 10 in the right ventricle. As illustrated, the lead 34 is fed through the inferior vena cava 27, into the right atrium 16, and then into the right ventricle 12 as illustrated. As will be appreciated by those skilled in the art, a second path for lead 34 could alternatively be 15 through the superior vena cava 20, into the right atrium 16, and then into the right ventricle 12.

20       The second lead 36, which will be described in greater detail with respect to Figures 7 and 8, generally includes a first or tip electrode 42, a second or ring electrode 44, and a third electrode 46. As illustrated, 25 the second lead 36 is flexible and arranged to be passed down the superior vena cava 20, into the right atrium 16, into the coronary sinus ostium 24, and advanced into the coronary sinus 22 of the heart near the left side thereof so that the first or tip electrode 42 is within the 30 coronary sinus adjacent the left ventricle 14. The electrodes 42, 44, and 46 are spaced apart such that when the first electrode 42 is within the coronary sinus 22 adjacent the left ventricle 14, the second electrode 44 is beneath the left atrium 18 near the left ventricle 14 and the third electrode 46 is in a region adjacent to the 35 right atrium coronary sinus ostium 24 within either the right atrium 16 or the superior vena cava 20. The first electrode 42 and the second electrode 44 enable bi-polar sensing of electrical activations of the left ventricle 14. The second electrode 44 together with the third electrode 46 provide bi-polar sensing of heart activity in the atria 16 and 18. The second electrode 44 and the

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third electrode 46 further provide for the delivery of defibrillating electrical energy of the atria. Because the second electrode 44 is located beneath the left atrium 18 near the left ventricle 14 and the third electrode 46 5 is within either the right atrium 16 or the superior vena cava 20 and above the coronary sinus ostium 24, the electrical energy applied between these electrodes will be substantially confined to the atria 16 and 18 of the heart 10. As a result, the electrical energy applied to the 10 right ventricle 12 and left ventricle 14 when the atria are cardioverted or defibrillated will be minimized. This greatly reduces the potential for ventricular fibrillation 15 of the heart to be induced as a result of the application of defibrillating electrical energy of the atria of the heart.

Within the enclosure 32, the atrial defibrillator 30 includes a first sense amplifier 50, a second sense amplifier 52, and a third sense amplifier 54. The first sense amplifier 50 forms a first sensing means 20 which, when inputs 50a and 50b are coupled to electrodes 38 and 40 respectively of the first lead 34, senses electrical activations of the right ventricle 12. The second sense amplifier 52 forms a second sensing means which, when inputs 52a and 52b are coupled to electrodes 25 42 and 44 respectively of the second lead 36, senses electrical activations of the left ventricle 14. The third sense amplifier 54 forms atrial sense means which, when inputs 54a and 54b are coupled to electrodes 44 and 30 46 respectively of the second lead 36, senses atrial activity of the heart when enabled as will be described hereinafter.

The outputs of the first and second sense amplifiers 50 and 52 are coupled to first and second R wave detectors 56 and 58 respectively. Each of the 35 R wave detectors 56 and 58 is of the type well known in the art which provides an output pulse upon the occurrence of an R wave being sensed during a cardiac cycle of the heart. The output of the third sense amplifier 54 is

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coupled to an analog to digital converter 60 which converts the analog signal representative of the atrial activity of the heart being sensed to digital samples for processing when the analog to digital converter 60 is 5 enabled also in a manner to be described hereinafter.

The enclosure 32 of the atrial defibrillator 30 further includes a microprocessor 62. The microprocessor 62 is preferably implemented in a manner to be described hereinafter with respect to the flow diagrams of Figures 10 2 through 6. The implementation of the microprocessor 62 results in a plurality of functional stages. The stages include a first timer 64, a second timer 66, a third timer 68, a synchronization marker controller 70, and a synchronization detector 72. The functional stages of the 15 microprocessor 62 further include a calculator stage including an average calculation stage 74, a standard deviation calculation stage 76, an enable stage 78, a disable stage 80, an atrial arrhythmia detector in the form of an atrial fibrillation detector 82, a first counter 84, a second counter 86, a third counter 88, and a charge delivery and energy control stage 90.

The microprocessor 62 is arranged to operate in conjunction with a memory 92. The memory 92 is coupled to the microprocessor 62 by a multiple-bit address bus 94 and a bi-directional multiple-bit databus 96. The address bus 94 permits the microprocessor 62 to address desired memory locations within the memory 92 for executing write or read operations. During a write operation, the microprocessor stores data, such as time intervals or operating 25 parameters in the memory 92 at the addresses defined by the multiple-bit addresses conveyed over bus 94 and conveys the data to the memory 92 over the multiple-bit bus 96. During a read operation, the microprocessor 62 obtains data from the memory 92 from the storage locations 30 identified by the multiple-bit addresses provided over bus 94 and receives the data from the memory 92 over the bi-directional bus 96.

For entering operating parameters into the memory 92, the microprocessor 62 receives programmable operating parameters from an external controller 100 which is external to the skin of the patient. The external controller 100 is arranged to communicate with a receiver/transmitter 102 which is coupled to the microprocessor 62 over a bi-directional bus 104. The receiver/transmitter 102 may be of the type well known in the art for conveying various information which it obtains from the microprocessor 62 to the external controller 100 or for receiving programming parameters from the external controller 100 which the receiver/transmitter 102 then conveys to the microprocessor 62 for storage in the memory 92. To that end, the memory 92 includes a mode selection portion 98 for storing mode selection information to be described hereinafter.

The receiver/transmitter 102 includes a transmitting coil 106 so that the receiver/transmitter 102 and coil 106 form a communication means. Such communication means are well known in the art and may be utilized as noted above for receiving commands from external to the implantable enclosures 32 and for transmitting data to the external controller 100 from the implanted enclosure 32. One such communication system is disclosed, for example, in U.S. Patent No. 4,586,508.

To complete the identification of the various structural elements within the enclosure 32, the atrial defibrillator 30 further includes a pacer output stage 108. As will be seen hereinafter, the pacer output stage 108 applies stimulating pulses to the right ventricle 12 of the heart 10 when bradycardia pacing is required or synchronization marker pulses to the right ventricle when the atrial defibrillator is in the marker pulse mode. The atrial defibrillator 30 further includes a charger and storage capacitor circuit 110 of the type well known in the art which charges a storage capacitor to a predetermined voltage level and a discharge circuit 112 for discharging the storage capacitor within circuit 110

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by a predetermined amount to provide a controlled discharge output of electrical energy when required to the atria of the heart. To that end, the discharge circuit 112 includes outputs 112a and 112b coupled to electrodes 5 46 and 44 respectively of the second lead 36 for applying the cardioverting or defibrillating electrical energy to the atria. Lastly, the defibrillator 30 includes a depletable power source 114, such a lithium battery, for providing power to the electrical components of the atrial 10 defibrillator 30. As will be seen hereinafter, the atrial defibrillator 30 is arranged to minimize the power consumption of the battery 114 so as to extend the useful life of the atrial defibrillator 30.

The operation of the atrial defibrillator 30 and 15 more particularly the operation of the functional stages residing within the enclosure 32 will now be described with reference to the flow diagrams of Figures 2-6. Referring now to Figure 2, it illustrates the manner in which the atrial defibrillator 30 may be implemented in 20 accordance with the present invention for providing bradycardia pacing of the right ventricle 12 of the heart 10 and the determining of the time intervals between electrical activations of the right ventricle or bradycardia pacing pulses of the right ventricle. This 25 process begins with the resetting of the first timer 64 in step 120. The microprocessor then, in step 122, determines whether an R wave has been detected at the right ventricle. If an R wave has not been detected at the right ventricle, the processor then determines in step 30 124 if the first timer 64 has expired. If the first timer 64 has not expired, the processor returns to step 122 to determine whether an R wave has been detected at the right ventricle. If an R wave or electrical activation has been detected at the right ventricle, the processor then in 35 step 123 determines the time (T) since the first timer 64 was last reset and stores that time interval in the memory 92. The processor then returns to step 120 to reset the first timer 64.

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If in step 124 the processor had determined that the first timer 64 had expired, it would proceed to step 126 to pace the right ventricle. In so doing, the microprocessor activates the pacer output 108 and causes 5 the pacer output 108 to provide an electrical stimulating pulse to the electrodes 38 and 40 of the first lead 34. The timeout time of the first timer 64 may be, for example, one second and may be programmed into the memory 92 through the external controller 100 and the 10 receiver/transmitter 102.

Upon the pacing of the right ventricle in step 126, the processor then in step 128 determines the time on the first timer 64 and stores that time as a determined time interval. The processor then returns to step 120 to 15 once again reset the first timer.

As can thus be seen, the atrial defibrillator 30 provides bradycardia pacing of the right ventricle 12 and, upon each electrical activation being sensed at the right ventricle, determines the time interval since the first 20 timer 64 was reset by either a sensed electrical activation of the right ventricle or a stimulating pulse being delivered to the right ventricle during bradycardia pacing. Hence, in determining the time intervals, the sensed electrical activations of the right ventricle and 25 the delivery of a stimulating pacing pulse to the right ventricle are considered to be equivalent events in that each results in a depolarization of the right ventricle.

Referring now to Figure 3, it illustrates the manner in which the atrial defibrillator 30 may be 30 implemented for enabling the atrial fibrillation detector 82. This process begins at step 130 wherein the microprocessor first determines whether the right ventricle has been paced by the pacer output 108. If the right ventricle has not been paced, the processor proceeds 35 to step 132 to determine whether an R wave has been detected at the right ventricle. If an R wave has not been detected at the right ventricle, the processor returns to step 130 to once again determine whether the

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right ventricle has been paced. If the right ventricle has been paced as determined in step 130 or if an R wave has been detected at the right ventricle in step 132, the processor then proceeds to step 134 to calculate an 5 average time interval using the last 20 stored time interval values. This is performed by the average calculation stage 74 of the microprocessor 62.

After calculating the average time interval over the last twenty stored values of the time interval, the 10 processor then proceeds to step 136 to calculate the standard deviation of the average time interval calculated in step 134 for the last twenty stored values of the time interval. The standard deviation is calculated in the standard deviation calculation stage 76.

15 After calculating both the average time interval for the last twenty stored values of the time interval and the standard deviation for the average time interval for the last twenty stored values of the time interval, the processor then proceeds to step 138 to determine if the 20 average time interval calculated in step 134 is less than or equal to a first predetermined time interval of, for example, 500 milliseconds. If the average time interval calculated in step 134 is not less than or equal to 500 milliseconds, the processor then returns to step 130 to 25 once again determine whether the right ventricle has been paced.

If in step 138 the processor determines that the average time interval calculated in step 134 is less than or equal to 500 milliseconds, the processor then proceeds 30 to step 140 to determine if the standard deviation calculated in step 136 is greater than or equal to a predetermined standard deviation of, for example, twenty milliseconds. If the standard deviation calculated in step 136 is not greater than or equal to twenty 35 milliseconds, the processor returns to step 130 to once again determine whether the right ventricle has been paced. However, if the standard deviation calculated in step 136 is greater than or equal to the predetermined

standard deviation of, for example, twenty milliseconds, the processor then proceeds to step 142 to enable the atrial fibrillation detector. This step is performed through the enable stage 78 which enables the atrial 5 fibrillation detector 82, the analog-to-digital converter 60, and the third sense amplifier 54 over a control line 55. This causes the atrial fibrillation detector 82, the analog-to-digital converter 60, and the third sense amplifier 54 to be activated.

10 As can thus be seen by the implementation illustrated in Figure 3, the atrial defibrillator 30 activates the atrial fibrillation detector 82, the analog-to-digital converter 60, and the third sense amplifier 54 responsive to the determined time intervals, and 15 preferably, the last twenty time intervals stored in the memory 92. This allows the atrial fibrillation detector 82, the analog-to-digital converter 60, and the third sense amplifier 54 to be normally disabled to avoid excessive consumption of the battery 114. This is 20 particularly important because the algorithms utilized in arrhythmia detectors, such as fibrillation detectors, consume considerable power and if left continuously energized, would require frequent replacement of the defibrillators in which they are employed for the purpose 25 of replacing the depletable power sources, such as a battery.

The criteria utilized for activating the atrial fibrillation detector is both the average heart rate and the variability of the heart rate. By utilizing this 30 criteria, the atrial fibrillation detector need only be activated when there is a probability that atrial fibrillation is present to thus permit the atrial fibrillation detector, the analog-to-digital converter 60, and the third sense amplifier 54 to be normally disabled 35 for conserving the power of the depletable power source.

Thus far, it will also be noted that only the right ventricle is being sensed. Only electrical activations of the right ventricle are sensed for either

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providing bradycardia pacing of the right ventricle or for enabling the atrial fibrillation detector. This assures that little power is consumed during the times in which neither bradycardia pacing is required or in which there 5 is a low probability that atrial fibrillation is present in the heart.

In accordance with this preferred embodiment, the atrial fibrillation detector 82, the analog-to-digital converter 60, and the third sense amplifier 54 may also be activated manually from external to the patient's skin. 10 This external activation may be accomplished by, for example, the patient's physician sending suitable commands from the external controller 100. The commands would then be received by the receiver/transmitter 102 and conveyed 15 to the microprocessor 62 which would then, in response to the received command, activate the atrial fibrillation detector 82, the analog-to-digital converter 60, and the third sense amplifier 54.

Referring now to Figure 4, it illustrates the 20 manner in which the atrial defibrillator 30 may be implemented for detecting the occurrence of atrial fibrillation in the heart and for enabling either the atrial defibrillation output or the right ventricle marker output of the atrial defibrillator.

This process begins at step 150 wherein the 25 microprocessor resets the second timer 66. The processor then proceeds to step 152 to determine whether atrial fibrillation is detected. Here it is assumed that the average time interval calculated in step 134 for the last twenty values of the stored time intervals was less than 30 or equal to 500 milliseconds and that the standard deviation of the average time interval for the last twenty stored values of the time intervals was greater than 20 milliseconds as calculated in step 136 and determined in 35 step 140 to cause the atrial fibrillation detector 82, the analog to digital converter 60, and the third sense amplifier 54 to be activated by the control line 55. Atrial fibrillation may be detected by the microprocessor

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through processing the digitized values of the atrial activity provided by the analog to digital converter 60. As previously mentioned, the atrial activity is sensed by the second electrode 44 and third electrode 46 of the 5 second lead 36 and the third sense amplifier 54.

There are many algorithms known in the art for processing such data to determine if fibrillation is present. One such algorithm is disclosed in a paper: Nitish V. Thakor, Yi-Sheng Zhu and Kong-Yan Pan, 10 "Ventricular Tachycardia and Fibrillation Detection by a Sequential Hypothesis Testing Algorithm," IEEE Transactions On Biomedical Engineering," Vol. 37, No. 9, pp. 837-843, September 1990. Another such algorithm is disclosed in a paper: Janice Jenkins, Ki Hong Noh, Alain 15 Guezennec, Thomas Bump, and Robert Arzbaecher, "Diagnosis of Atrial Fibrillation Using Electrograms from Chronic Leads: Evaluation of Computer Algorithms," PACE, Vol. 11, pp. 622-631, May 1988. Implementing such algorithms by a microprocessor such as microprocessor 62 is well within 20 the preview of one skilled in the art.

If in step 152 it is determined that atrial fibrillation is not currently taking place in the heart, the microprocessor then proceeds to step 154 to determine whether the second timer 66 has expired. If the second 25 timer has not expired, the processor returns to step 152 to again determine whether atrial fibrillation is currently taking place in the heart. If in step 154 it is determined that the second timer 66 has expired, the processor then proceeds to step 156 to disable the atrial fibrillation detector. This step is performed after a 30 predetermined expiration time of the timer 66, which may be, for example, six seconds.

If the atrial defibrillator in step 152 determines that atrial fibrillation is currently present 35 in the heart, the microprocessor then proceeds to determine whether it is able to obtain a reliable synchronizing pulse for synchronizing the delivery of the defibrillating or cardioverting electrical energy to the

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atria. This begins in step 158 where the atrial defibrillator microprocessor determines whether an electrical activation has been detected in the right ventricle. If an R wave has not been detected in the 5 right ventricle, the microprocessor performs a loop to once again determine at step 158 if an R wave has been detected in the right ventricle. When an R wave is detected in the right ventricle, the microprocessor proceeds to step 160 to start the third timer 68. After 10 starting timer 68, the processor then proceeds to step 162 to determine whether an R wave has been detected in the left ventricle. If an electrical activation has not been detected at the left ventricle, the microprocessor then returns to step 162 to once again determine whether an R 15 wave has been detected at the left ventricle. When an R wave is detected at the left ventricle, the microprocessor then proceeds to step 164 to stop the third timer 68. In so doing, the third timer 68 will have the time from when the R wave was detected at the right ventricle in step 158 20 and when the same R wave was detected at the left ventricle in step 162.

The microprocessor then proceeds to step 166 to determine if the time between the detection of the electrical activation at the right ventricle and at the 25 left ventricle is within a range of normal delay times between depolarization activation waves being sensed at the right ventricle and the left ventricle. The predetermined range may be established by programming the range into the memory 92 from the external controller, 30 through the receiver/transmitter 102 and the microprocessor 62. The normal delay times may, for example, range from 5 milliseconds to 30 milliseconds. As a result, in step 166, the microprocessor determines whether the time between the sensing of the electrical activation and the right ventricle and in the left 35 ventricle was greater than 5 milliseconds and less than 30 milliseconds. If it was not, this is considered to be a negative test resulting in an unreliable synchronizing

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5 detection. In this event, the microprocessor proceeds to step 168 to increment the first counter 84. The microprocessor then proceeds to step 170 to determine whether the count in the first counter 84 is equal to a predetermined count, of, for example, five. If it is not, the processor then resets the third timer 68 in step 172 and returns to step 158 to detect another R wave at the right ventricle for detecting whether a reliable synchronizing pulse may be detected. When the count 10 within the first counter 84 reaches the predetermined count of five, the processor then proceeds to step 174 to disable the atrial fibrillation detector 82. Both this step and step 156 may be performed by the disable stage 80 providing a disable signal over the control line 55 for 15 disabling the atrial fibrillation detector, the analog to digital converter 60, and the third sense amplifier 54.

20 As can be seen from the foregoing, the atrial defibrillator will go no further in its processing even though atrial fibrillation has been detected if it is not assured that a reliable synchronization pulse could be generated for synchronizing the delivery of the defibrillating or cardioverting electrical energy to the atria in synchronism with an electrical activation of the heart. This also, as will be seen hereinafter, negates 25 the need for activating the charging circuit 110 for charging the storage capacitor if a defibrillating pulse could not be reliably applied in synchronism with an electrical activation of the heart to further conserve the depletable power source of the battery 114.

30 In determining whether a reliable synchronization pulse can be derived, and as will be seen hereinafter, in providing a synchronization pulse, the atrial defibrillator first senses a depolarization activation wave at a first area of the heart and senses 35 the same depolarization activation wave at a second area of the heart. In accordance with this preferred embodiment, the first area of the heart is the right ventricle and the second area of the heart is the left

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ventricle. If the activation wave at the right and left ventricle is detected coincidentally as will be determined in step 166, or detected at times too far apart to be considered a legitimate electrical activation wave, a 5 synchronization pulse will not be derived nor will such detection be considered a positive test of the ability to derive such a synchronization pulse. The foregoing is based upon the fact electrical activation depolarization waves propagate across the heart so that the sensing of an 10 electrical activation at two different areas of the heart should occur at different times while noise, which may be mistaken for an electrical activation, would be detected at both areas of the heart simultaneously. As a result, the non-coincident sensing of an electrical activation at 15 two different areas of the heart such as at the right ventricle and the left ventricle provide a reliable indication that the sensed electrical activation is a real or legitimate electrical activation and can be relied upon for deriving a reliable synchronization pulse for 20 synchronizing the delivery of a defibrillating or cardioverting electrical pulse to the atria in synchronism with an electrical activation of the heart.

Referring again to Figure 4, if in step 166 it is determined that there has been non-coincident sensing 25 of an electrical activation at the right ventricle and the left ventricle by determining that such sensing occurred within a time greater than 5 milliseconds and less than 30 milliseconds, the microprocessor proceeds to step 176 to reset the third timer 68. After resetting timer 68, the 30 microprocessor then determines in step 178 if the atrial defibrillator is set in the defibrillating mode. In performing this step, the microprocessor accesses the contents of a known storage location in the mode selection portion 98 of memory 92 to determine, for example, if that 35 bit is set or not set. For example, if the bit is set this may be considered by the microprocessor as indicating that the atrial defibrillator is set in the defibrillating mode. If the bit is not set, the microprocessor may

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consider this as indicating that the atrial defibrillator is in the right ventricle marker mode and not the atrial defibrillating mode. Hence, if it is determined in step 178 that the atrial defibrillator is in the atrial defibrillating mode, it will then in step 180 enable the charge delivery and energy control stage 90. If the atrial defibrillator is not in the atrial defibrillating mode, the microprocessor will then enable the sync marker controller 70 in step 182.

10 Referring now to Figure 5, it illustrates the manner in which the atrial defibrillator 30 may be implemented for providing marker sync pulses to the right ventricle 12 of the heart 10. The foregoing assumes that in step 178, the microprocessor determined that the atrial defibrillator was in the marker pulse mode and has enabled the sync marker controller 70.

20 This process begins at step 190 with the microprocessor resetting the third timer 68. The microprocessor then proceeds to step 192 to determine whether an R wave has been detected at the right ventricle. If an R wave has not been detected, the microprocessor continues to determine whether an R wave has been detected at the right ventricle until an R wave is detected. When an R wave is detected at the right ventricle, the microprocessor then proceeds to step 194 to start the third timer 68. It then advances to step 196 to determine whether the R wave has been detected at the left ventricle. If the R wave has not been detected at the left ventricle, the microprocessor continues to determine 30 whether an R wave has been detected at the left ventricle and when the R wave has been detected at the left ventricle, the microprocessor then at step 198 stops the third timer 68. After stopping timer 68, the microprocessor then proceeds to step 200 to determine if the time between the sensing of the R wave at the right ventricle and at the left ventricle occurred within a time 35 greater than 5 milliseconds and less than 30 milliseconds. If it has not, the detected R wave is considered to be

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either noise or an unreliable detection and the microprocessor returns to step 190 to reset the third timer 68. If, however, the microprocessor determines in step 200 that the R wave was detected at the right 5 ventricle and the left ventricle within the normal delay time range of 5 milliseconds and 30 milliseconds, the microprocessor then proceeds to step 202 to pace the right ventricle with a marker pulse. This step is performed by the sync detector 72 providing a sync pulse to the sync 10 marker controller 70 and the sync marker controller 70 causing the pacer output 108 to pace the right ventricle.

After the right ventricle is paced with the marker pulse, the microprocessor proceeds to step 204 to increment the second counter 86. The microprocessor then 15 proceeds to step 206 to determine whether the second counter 86 has reached a predetermined count of, for example, 60 marker pulses. If it has not, the microprocessor returns to step 190 to reset the third timer 68 and to detect another electrical activation of 20 the heart for providing a synchronizing pulse. If the count in the second counter 86 has reached the predetermined number of marker pulses counted, such as 60 pulses, the microprocessor then proceeds to step 208 to disable the sync marker controller 70 and to terminate the 25 provision of the marker pulses to the right ventricle.

As can be seen by the foregoing, the atrial defibrillator 30 is arranged to provide marker pulses to enable a physician to determine whether proper operating parameters have been established within the atrial defibrillator for reliably detecting electrical 30 activations to provide reliable synchronizing pulses. The marker pulses provided to the right ventricle are preferably of a relatively low energy, and of an energy which is insufficient to cardiovert or defibrillate the 35 heart but which may be sufficient for pacing the right ventricle of the heart. For example, the quantity of electrical energy utilized in each marker pulse may have an energy in the range of 5 to 50 microjoules and

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preferably 25 microjoules. Marker pulse energies of, for example, 25 microjoules, although being sufficient to pace the right ventricle of the heart, would not adversely affect normal heart rhythm in as much as the marker pulses 5 are being provided in synchronism with detected electrical activations of the heart and more particularly, reliably detected activations of the heart in accordance with the present invention. The marker pulses, if applied in the range of energies noted above, will have energies 10 sufficient so as to be detected on an electrocardiogram generated externally to the skin of the patient by a physician in a known manner.

Referring now to Figure 6, it illustrates the manner in which the atrial defibrillator 30 may be 15 implemented for applying cardioverting or defibrillating energy to the atria 16 and 18 of the heart 10. For this description, it is assumed that in step 178 the microprocessor determined that the atrial defibrillator was in the atrial defibrillating mode and that the charge 20 delivery and energy control stage 90 had been activated by the microprocessor.

This process begins at step 210 with the charge delivery and energy control stage 90 providing over control line 111 an enable signal to enable the charger to 25 charge the storage capacitor of the charger and storage capacitor circuit 110. The microprocessor then proceeds to step 212 to reset the third counter 88 which, as will be seen hereinafter, is utilized to count synchronizing pulses. The processor then proceeds to step 214 to reset 30 the third timer 68. After resetting the third timer 68, the processor proceeds to step 216 to determine whether an R wave has been detected at the right ventricle. If an R wave has not been detected at the right ventricle, the microprocessor continues to determine whether an R wave 35 has been detected at the right ventricle and when one is detected, the microprocessor proceeds to step 218 to start the third timer 68. After starting the third timer 68, the microprocessor proceeds to step 220 to determine

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whether the R wave has been detected at the left ventricle. If the R wave has not been detected at the left ventricle, the processor continues to determine whether the R wave has been detected at the left ventricle and when it is detected, the microprocessor in step 222 stops the third timer 68. After stopping the third timer 68, the microprocessor then in step 224 determines whether the detection of the R wave at the right ventricle and at the left ventricle occurred within the normal range of delay times of five milliseconds to 30 milliseconds. If it had not been so detected, the microprocessor then returns to step 212 to reset the third counter 88. If the R wave had been detected at the right ventricle and the left ventricle within the normal delay time, the microprocessor then proceeds to step 226 to increment the third counter 88. After incrementing the third counter 88, the microprocessor determines in step 228 if the third counter has reached a count of five. If it has not, the microprocessor returns to step 214 to once again reset the third timer 68 for detecting another electrical activation of the heart. When the third counter reaches a predetermined count of, for example, five counts, the microprocessor then proceeds to step 230 for discharging the capacitor of circuit 110. The discharging of the capacitor is controlled by the discharge circuit 112 and the discharge duration is determined by a signal carried on a control line 113 to control the duration of the discharge and thus the quantity of electrical energy delivered to the atria of the heart. The defibrillating or cardioverting energy is delivered between the second electrode 44 and the third electrode 46 of the second lead 36 to confine the cardioverting or defibrillating energy to the atria of the heart. The quantity of energy delivered to the atria for cardioverting or defibrillating the atria may be in the range of .1 to 3 joules. The actual quantity of defibrillating energy required will vary from patient to patient but, in the majority of the cases, will fall within the range of .1 to 3 joules.

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After applying the defibrillating energy to the atria of the heart, the microprocessor then proceeds to step 232 to disable the charge delivery and energy control stage 90. Lastly, the microprocessor then proceeds to 5 step 234 to disable the atrial fibrillation detector 82.

From the foregoing, it can be seen that five consecutive reliable synchronizing pulses must be provided by the sync detector 72 before defibrillating or cardioverting electrical energy is applied to the atria of 10 the heart to assure reliable synchronization. Upon the fifth synchronizing pulse, the defibrillating or cardioverting electrical energy is then applied to the atria of the heart which will occur in synchronism with the last one of the predetermined number of electrical 15 activations detected by the sync detector 72. As a result, reliable synchronization of the defibrillating or cardioverting electrical energy with a detected electrical activation of the heart will be assured.

Once the atrial fibrillation detector is 20 disabled in step 234, the atrial defibrillator returns to once again determine the probability of atrial fibrillation and, if there is a probability of atrial fibrillation, to once again enable the atrial fibrillation detector. This begins the implementation of the atrial 25 defibrillator as illustrated in the flow diagrams of Figures 4-6.

Referring now to Figure 7, it illustrates the intravascular second lead 36 which is structured in accordance with another aspect of the present invention. 30 As will be noted, the lead 36 includes the first or tip electrode 42, the second or ring electrode 44, and the third electrode 46. Hence, the second electrode is proximal to the tip electrode 42, and the third electrode 46 is proximal to the second electrode 44 with the first 35 electrode 42 being at the distal end of the lead.

The lead 36 also includes a connector 45 at its proximal end having a first contact 42a, a second contact 44a, and a third contact 46a. The connector 45 is

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preferably arranged for being matingly received by a complimentary receptacle of the enclosure 32 of the atrial defibrillator 30. The lead 36 includes three conductors which are illustrated in Figure 8. Here it can be seen  
5 that the first conductor 42b, the second conductor 44b, and the third conductor 46b are coaxially disposed to one another with the first conductor 42b being a center conductor, the second conductor 44b being an inner conductor, and the third conductor 46b being an outer conductor.  
10 The conductors are arranged such that the first conductor 42b connects the first contact 42a with the first electrode 42, the second conductor 44b connects the first contact 44a with the second electrode 44, and the third conductor 46b connects the third contact 46a with the third electrode 46. It will also be noted that  
15 the lead 36, although being flexible, includes a preshaped portion and is preshaped to generally conform to the shape of the coronary sinus of the heart in which the lead is arranged to be advanced. The preshaping of the electrode  
20 in portion 47 assures that the distal end or tip electrode 42 will advance to within the coronary sinus adjacent the left ventricle. As previously mentioned, when the first electrode is within the coronary sinus adjacent the left ventricle, the second electrode 44 is beneath the left  
25 atrium near the left ventricle and the third electrode is within the right atrium or the superior vena cava.

Referring now to Figure 9, it illustrates, in perspective view, a human heart 10 having a lead system 250, configured in accordance with a first lead system preferred embodiment of the present invention implanted therein. The portions of the heart 10 particularly noted in Figure 9 are the right ventricle 12, the left ventricle 14, the right atrium 16, the left atrium 18, the superior vena cava 20, the coronary sinus 22, the great vein 23, 30 and the inferior vena cava 27.  
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The lead system 250 generally includes a first lead 252 and a second lead 254. The leads 252 and 254 are flexible but preformed so that the leads 252 and 254 may

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be readily fed into the heart 10 and assume the configurations when implanted as illustrated in the Figure.

5       The first lead 252 carries or includes a first elongated, large surface area, electrode 256, a distal or tip sense electrode 258, and a ring or proximal sense electrode 260. The electrodes 258, 260, and 256 are spaced apart on the lead 252 so that, when lead 252 is fed into the superior vena cava 20 and into the right 10 ventricle 12 through the right atrium 16 to a position where electrode 258 is at the apex of the right ventricle, the first elongated electrode 256 will be disposed in and in electrical contact with the right atrium 16 of the heart 10. Also, electrodes 258 and 260 will be in 15 electrical contact with the right ventricle of the heart 10.

The second lead 254 includes a second elongated, large surface area, electrode 262, a tip or distal sense electrode 264, and a ring or proximal sense electrode 266. 20       The electrodes 264, 266, and 262 are spaced apart on the second lead 254 so that when the lead 254 is fed into the superior vena cava 20 and into a coronary vein, such as the great vein 23 through the right atrium 16 and the coronary sinus 22 with electrodes 264 and 266 being 25 adjacent the left ventricle within the great vein as illustrated, the second elongated electrode 262 will be disposed within the coronary sinus 22 just beneath the left atrium 18 and adjacent to the left ventricle 14. Since the coronary sinus 22 is in close proximity to the 30 left atrium 18 and the left ventricle 14, electrodes 264 and 266 will be in electrical contact with the left ventricle and electrode 262 will be in electrical contact with the left atrium 18.

35       Blood flow within the great vein 23 and the coronary sinus 22 is in an upward direction and hence would tend to push the lead 254 from the implanted position as illustrated and described above. Hence, to assure fixation of lead 254 in place, the lead 254 is

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preferably provided with a preformed bend at 255 where the lead 254 exits the coronary sinus 22 and enters a coronary vein, such as the great vein 23.

The lead system 250 may be utilized to advantage in association with the atrial defibrillator 30 illustrated in Figure 1 for monitoring the activity of the heart 10 and for delivering cardioverting or defibrillating electrical energy to the atria 16 and 18 of the heart 10. To that end, the first elongated electrode 256 may be coupled to input 54a of sense amplifier 54 and to output 112a of the discharge circuit 112. The second elongated electrode 262 may be coupled to input 54b of sense amplifier 54 and to output 112b of discharge circuit 112. With such coupling, electrodes 256 and 262 may be utilized for sensing atrial activity of the heart in association with sense amplifier 54. Also, the cardioverting electrical energy provided from the charger and storage capacitor 110 and the discharge circuit 112 will be received by electrodes 256 and 262 for applying the electrical cardioverting energy between the right atrium 16 and the coronary sinus 22 beneath the left atrium 18 and adjacent to the left ventricle 14 to deliver the cardioverting electrical energy to the atria 16 and 18 of the heart 10. By virtue of the locations of the elongated stimulating electrodes 256 and 262, the electrical energy applied to the right ventricle 12 and left ventricle 14 when the atria are cardioverted or defibrillated will be minimized.

For sensing electrical activations of the heart, the first pair of sensing electrodes 258 and 260 carried by the first lead 252 may be coupled to inputs 50a and 50b respectively of sense amplifier 50 and the second pair of sensing electrodes 264 and 266 of the second lead 254 may be coupled to inputs 52a and 52b respectively of sense amplifier 52. This permits sensing of electrical activations of the heart and more specifically electrical activations of the right ventricle 12 and electrical activations of the left ventricle 14. This enables the

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non-coincident sensing of the depolarization activation waves as previously described for synchronizing the delivery of the cardioverting or defibrillating electrical energy to the atria 16 and 18 in synchronism with a 5 detected electrical activation of the heart.

Referring now to Figure 10, it illustrates, in perspective view, a human heart 10 having a lead system 270, configured in accordance with a second lead system preferred embodiment of the present invention, implanted 10 therein. The portions of the heart 10 particularly noted in Figure 10 are the right ventricle 12, the left ventricle 14, the right atrium 16, the right atrial appendage 17, the left atrium 18, the superior vena cava 20, the coronary sinus 22, the great vein 23, and the 15 inferior vena cava 27.

The lead system 270 generally includes a first lead 272 and a second lead 274. The leads 272 and 274 are flexible but preformed so that the leads 272 and 274 may be readily fed into the heart 10 and assume the 20 configurations when implanted as illustrated in the Figure.

The first lead 272 carries or includes a first elongated, large surface area, electrode 276, a distal or tip sense electrode 278, and a ring or proximal sense electrode 280. The electrodes 278, 280, and 276 are 25 spaced apart on the lead 272 so that when lead 272 is fed into the superior vena cava 20 and into the right ventricle 12 through the right atrium 16 to a position where electrode 278 is at the apex of the right ventricle, 30 the first elongated electrode 276 will be disposed in and in electrical contact with the right atrium 16 of the heart 10. It will be further noted that the lead 270 is looped or pigtailed in the region of electrode 276 so that the electrode 276 is disposed in the right atrial appendage 17. Also, electrodes 278 and 280 will be in 35 electrical contact with the right ventricle of the heart 10.

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The second lead 274 includes a second elongated, large surface area, electrode 282, a tip or distal sense electrode 284, and a ring or proximal sense electrode 286. The electrodes 284, 286, and 282 are spaced apart on the 5 second lead 274 so that when the lead 274 is fed into the superior vena cava 20 and into a coronary vein such as the great vein 23 through the right atrium 16 and coronary sinus 22 with electrodes 284 and 286 being adjacent the left ventricle within the great vein 23 as illustrated, 10 the second elongated electrode 282 will be disposed within the coronary sinus 22 just beneath the left atrium 18 and adjacent to the left ventricle 14. Since the coronary sinus 22 is in close proximity to the left atrium 18 and the left ventricle 14, electrodes 284 and 286 will be in 15 electrical contact with the left ventricle and electrode 282 will be in electrical contact with the left atrium 18.

Blood flow within the great vein 23 and the coronary sinus 22 is in an upward direction and hence would tend to push the lead 274 from the implanted 20 position as illustrated and described above. Hence, to assure fixation of lead 274 in place, the lead 274 is preferably provided with a preformed bend at 275 where the lead 274 exits the coronary sinus 22 and enters a coronary vein, such as the great vein 23.

The lead system 270 may be utilized to advantage 25 in association with the atrial defibrillator 30 illustrated in Figure 1 for monitoring the activity of the heart 10 and for delivering cardioverting or defibrillating electrical energy to the atria 16 and 18 of 30 the heart 10. To that end, the first elongated electrode 276 may be coupled to input 54a of sense amplifier 54 and to output 112a of the discharge circuit 112. The second elongated electrode 282 may be coupled to input 54b of sense amplifier 54 and to output 112b of discharge circuit 35 112. With such coupling, electrodes 276 and 282 may be utilized for sensing atrial activity of the heart in association with sense amplifier 54. Also, the cardioverting electrical energy provided from the charger

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and storage capacitor 110 and the discharge circuit 112 will be received by electrodes 276 and 282 for applying the electrical cardioverting energy between the right atrium 16 and the coronary sinus 22 beneath the left 5 atrium 18 and adjacent to the left ventricle 14 to deliver the cardioverting electrical energy to the atria 16 and 18 of the heart 10. By virtue of the locations of the elongated stimulating electrodes 276 and 282, the electrical energy applied to the right ventricle 12 and 10 left ventricle 14 when the atria are cardioverted or defibrillated will be minimized.

For sensing electrical activations of the heart, the first pair of sensing electrodes 278 and 280 carried by the first lead 272 may be coupled to inputs 50a and 50b 15 respectively of sense amplifier 50 and the second pair of sensing electrodes 284 and 286 of the second lead 274 may be coupled to inputs 52a and 52b respectively of sense amplifier 52. This permits sensing of electrical activations of the heart and more specifically electrical 20 activations of the right ventricle 12 and electrical activations of the left ventricle 14. This enables the non-coincident sensing of the depolarization activation waves as previously described for synchronizing the 25 delivery of the cardioverting or defibrillating electrical energy to the atria 16 and 18 in synchronism with a detected electrical activation of the heart.

Referring now to Figure 11, it illustrates, in perspective view, a human heart 10 having a lead system 290, configured in accordance with a third lead system 30 preferred embodiment of the present invention, implanted therein. The portions of the heart 10 particularly noted in Figure 11 are the right ventricle 12, the left ventricle 14, the right atrium 16, the left atrium 18, the superior vena cava 20, the coronary sinus 22, the great 35 vein 23, and the inferior vena cava 27.

The lead system 290 generally includes a first lead 292 and a second lead 294. The leads 292 and 294 are flexible but preformed so that the leads 292 and 294 may

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be readily fed into the heart 10 and assume the configurations when implanted as illustrated in the Figure.

The second lead 294 carries or includes a first tip or distal sense electrode 296, a second medial sense electrode 298, and a third proximal sense electrode 300. The electrodes 296, 298, and 300 are spaced apart on the lead 294 so that when lead 294 is fed into the superior vena cava 20 and into the right ventricle 12 through the right atrium 16 to a position where electrode 296 is at the apex of the right ventricle, all three of the electrodes 296, 298, and 300 will be disposed in and in electrical contact with the right ventricle 12 of the heart 10.

The second lead 292 includes a first elongated, large surface area, electrode 302 and second elongated, large surface area, electrode 304. The electrodes 302 and 304 are spaced apart on the first lead 292 so that when the lead 292 is fed into the superior vena cava 20 and into the coronary sinus 22 as illustrated through the right atrium 16 with the second elongated electrode 304 disposed within the coronary sinus 22 just beneath the left atrium 18 and adjacent to the left ventricle 14, the first elongated electrode 302 will be disposed in and in electrical contact with the right atrium 16. Since the coronary sinus 22 is in close proximity to the left atrium 18, electrode 304 will be in electrical contact with the left atrium 18. Lead 292 may also be provided with a preformed bend at 293 to assist in fixing lead 292 in place against blood flow in the coronary sinus 22.

The lead system 290 may be utilized to advantage in association with the atrial defibrillator 30 illustrated in Figure 1 for monitoring the activity of the heart 10 and for delivering cardioverting or defibrillating electrical energy to the atria 16 and 18 of the heart 10. To that end, the first elongated electrode 302 may be coupled to input 54a of sense amplifier 54 and to output 112a of the discharge circuit 112. The second

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elongated electrode 304 may be coupled to input 54b of sense amplifier 54 and to output 112b of discharge circuit 112. With such coupling, electrodes 302 and 304 may be utilized for sensing atrial activity of the heart in 5 association with sense amplifier 54. Also, the cardioverting electrical energy provided from the charger and storage capacitor 110 and the discharge circuit 112 will be received by electrodes 302 and 304 for applying the electrical cardioverting energy between the right 10 atrium 16 and the coronary sinus 22 beneath the left atrium 18 and adjacent to the left ventricle 14 to deliver the cardioverting electrical energy to the atria 16 and 18 of the heart 10. By virtue of the locations of the elongated stimulating electrodes 302 and 304, the 15 electrical energy applied to the right ventricle 12 and left ventricle 14 when the atria are cardioverted or defibrillated will be minimized.

For sensing electrical activations of the heart, a first pair of the sensing electrodes 296 and 298 carried 20 by the second lead 294 may be coupled to inputs 50b and 50a respectively of sense amplifier 50 and a second pair of the sensing electrodes 298 and 300 of the second lead 294 may be coupled to inputs 52b and 52a respectively of sense amplifier 52. This permits sensing of electrical 25 activations of the heart and more specifically electrical activations at two different areas of the right ventricle 12. This enables the non-coincident sensing of the depolarization activation waves as previously described for synchronizing the delivery of the cardioverting or 30 defibrillating electrical energy to the atria 16 and 18 in synchronism with a detected electrical activation of the heart.

Referring now to Figure 12, it illustrates, in perspective view, a human heart 10 having a lead system 35 310, configured in accordance with a fourth lead system preferred embodiment of the present invention, implanted wherein. The portions of the heart 10 particularly noted in Figure 12 are the right ventricle 12, the left

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ventricle 14, the right atrium 16, the right atrial appendage 17, the left atrium 18, the superior vena cava 20, the coronary sinus 22, the great vein 23, and the inferior vena cava 27.

5        The lead system 310 generally includes a first lead 312 and a second lead 314. The leads 312 and 314 are flexible but preformed so that the leads 312 and 314 may be readily fed into the heart 10 and assume the configurations when implanted as illustrated in the  
10      Figure.

15      The second lead 314 carries or includes a first tip or distal sense electrode 316, a second medial sense electrode 318, and a third proximal sense electrode 320. The electrodes 316, 318, and 320 are spaced apart on the lead 314 so that when lead 314 is fed into the superior vena cava 20 and into the right ventricle 12 through the right atrium 16 to a position where electrode 316 is at the apex of the right ventricle, all three electrodes 316, 318, and 320 will be disposed in and in electrical contact  
20      with the right ventricle 12 of the heart 10.

25      The first lead 312 includes a first elongated, large surface area, electrode 322 and a second elongated, large surface area, electrode 324. The electrodes 322 and 324 are spaced apart on the first lead 312 so that when the lead 312 is fed into the superior vena cava 20 and into the coronary sinus 22 as illustrated through the right atrium 16 with the second elongated electrode 324 disposed within the coronary sinus 22 just beneath the left atrium 18 and adjacent to the left ventricle 14, the  
30      first elongated electrode 322 will be disposed in and in electrical contact with the right atrium 16. Since the coronary sinus 22 is in close proximity to the left atrium 18, electrode 324 will be in electrical contact with the left atrium 18.

35      It will be noted that the lead 312 is looped or pigtailed in the right atrium 16 so that the first electrode 322 is disposed in the right atrial appendage 17. To assist in assuring that electrode 322 is in the

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right atrial appendage 17, the lead 312 is provided with a first preformed bend at 313 in the area where lead 312 enters the right atrium 16 from the superior vena cava 20 and a stiffened section 315 to force the electrode 322 5 against the inner wall of the right atrium 16 in the right atrial appendage 17. The lead 12 is further provided with a second preformed bend at 317 to assist in fixing lead 312 in place against blood flow in the coronary sinus 22.

The lead system 310 may be utilized to advantage 10 in association with the atrial defibrillator 30 illustrated in Figure 1 for monitoring the activity of the heart 10 and for delivering cardioverting or defibrillating electrical energy to the atria 16 and 18 of the heart 10. To that end, the first elongated electrode 15 322 may be coupled to input 54a of sense amplifier 54 and to output 112a of the discharge circuit 112. The second elongated electrode 324 may be coupled to input 54b of sense amplifier 54 and to output 112b of discharge circuit 112. With such coupling, electrodes 322 and 324 may be 20 utilized for sensing atrial activity of the heart in association with sense amplifier 54. Also, the cardioverting electrical energy provided from the charger and storage capacitor 110 and the discharge circuit 112 will be received by electrodes 322 and 324 for applying 25 the electrical cardioverting energy between the right atrium 16 and the coronary sinus 22 beneath the left atrium 18 and adjacent to the left ventricle 14 to deliver the cardioverting electrical energy to the atria 16 and 18 of the heart 10. By virtue of the locations of the 30 elongated stimulating electrodes 322 and 324, the electrical energy applied to the right ventricle 12 and left ventricle 14 when the atria are cardioverted or defibrillated will be minimized.

For sensing electrical activations of the heart, 35 a first pair of the sensing electrodes 316 and 318 carried by the second lead 314 may be coupled to inputs 50b and 50a respectively of sense amplifier 50 and a second pair of the sensing electrodes 318 and 320 of the second lead

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314 may be coupled to inputs 52b and 52a respectively of sense amplifier 52. This permits sensing of electrical activations of the heart and more specifically electrical activations at two different areas of the right ventricle 12. This enables the non-coincident sensing of the depolarization activation waves as previously described for synchronizing the delivery of the cardioverting or defibrillating electrical energy to the atria 16 and 18 in synchronism with a detected electrical activation of the heart.

Referring now to Figure 13, it illustrates, in perspective view, a human heart 10 having a lead system 330, configured in accordance with a fifth lead system preferred embodiment of the present invention, implanted therein. The portions of the heart 10 particularly noted in Figure 13 are the right ventricle 12, the left ventricle 14, the right atrium 16, the left atrium 18, the superior vena cava 20, the left pulmonary artery 21, and the inferior vena cava 27.

The lead system 330 generally includes a first lead 332 and a second lead 334. The leads 332 and 334 are flexible but preformed so that the leads 332 and 334 may be readily fed into the heart 10 and assume the configurations when implanted as illustrated in the Figure.

The second lead 334 carries or includes a first tip or distal sense electrode 336, a second medial sense electrode 338, and a third proximal sense electrode 340. The electrodes 336, 338, and 340 are spaced apart on the lead 334 so that when lead 334 is fed into the superior vena cava 20 and into the right ventricle 12 through the right atrium 16 to a position where electrode 336 is at the apex of the right ventricle, all three sense electrodes 336, 338, and 340 will be disposed in and in electrical contact with the right ventricle 12 of the heart 10.

The first lead 332 includes a first elongated, large surface area, electrode 342 and a second elongated,

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large surface area, electrode 344. The electrodes 342 and 344 are spaced apart on the first lead 332 so that when the lead 332 is fed into the superior vena cava 20 and into the left pulmonary artery 21 as illustrated through 5 the right atrium 16 and the right ventricle 12 with the second elongated electrode 344 disposed within the left pulmonary artery 21 adjacent to the left atrium 18, the first elongated electrode 342 will be disposed in and in electrical contact with the right atrium 16. Since the 10 left pulmonary artery 21 is in close proximity to the left atrium 18, electrode 344 will be in electrical contact with the left atrium 18. To assist in holding the lead 332 in place, the lead 332 is provided with a preformed bend at 333 where the lead 332 enters the right ventricle 15 12 from the right atrium 16.

The lead system 330 may be utilized to advantage in association with the atrial defibrillator 30 illustrated in Figure 1 for monitoring the activity of the heart 10 and for delivering cardioverting or 20 defibrillating electrical energy to the atria 16 and 18 of the heart 10. To that end, the first elongated electrode 342 may be coupled to input 54a of sense amplifier 54 and to output 112a of the discharge circuit 112. The second elongated electrode 344 may be coupled to input 54b of 25 sense amplifier 54 and to output 112b of discharge circuit 112. With such coupling, electrodes 342 and 344 may be utilized for sensing atrial activity of the heart in association with sense amplifier 54. Also, the cardioverting electrical energy provided from the charger 30 and storage capacitor 110 and the discharge circuit 112 will be received by electrodes 342 and 344 for applying the electrical cardioverting energy between the right atrium 16 and the left pulmonary artery 21 and adjacent to the left atrium 18 to deliver the cardioverting electrical 35 energy to the atria 16 and 18 of the heart 10. By virtue of the locations of the elongated stimulating electrodes 342 and 344, the electrical energy applied to the right

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ventricle 12 and left ventricle 14 when the atria are cardioverted or defibrillated will be minimized.

For sensing electrical activations of the heart, a first pair of the sensing electrodes 336 and 338 carried by the second lead 334 may be coupled to inputs 50b and 50a respectively of sense amplifier 50 and a second pair of the sensing electrodes 338 and 340 of the second lead 334 may be coupled to inputs 52b and 52a respectively of sense amplifier 52. This permits sensing of electrical activations of the heart and more specifically electrical activations at two different areas of the right ventricle 12. This enables the non-coincident sensing of the depolarization activation waves as previously described for synchronizing the delivery of the cardioverting or defibrillating electrical energy to the atria 16 and 18 in synchronism with a detected electrical activation of the heart.

Referring now to Figure 14, it illustrates, in perspective view, a human heart 10 having a lead system 350, configured in accordance with a sixth lead system preferred embodiment of the present invention, implanted therein. The portions of the heart 10 particularly noted in Figure 14 are the right ventricle 12, the left ventricle 14, the right atrium 16, the right atrial appendage 17, the left atrium 18, the superior vena cava 20, the coronary sinus 22, the great vein 23, and the inferior vena cava 27.

The lead system 350 generally includes a first lead 352, a second lead 354, and a third lead 356. The leads 352, 354, and 356 are flexible but preformed so that the leads 352, 354, and 356 may be readily fed into the heart 10 and assume the configurations when implanted as illustrated in the Figure.

The third lead 356 carries or includes a first tip or distal sense electrode 358, a second medial sense electrode 360, and a third proximal sense electrode 362. The electrodes 358, 360, and 362 are spaced apart on the lead 356 so that when lead 356 is fed into the superior

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5 vena cava 20 and into the right ventricle 12 through the right atrium 16 to a position where electrode 358 is at the apex of the right ventricle, all three sense electrodes 358, 360, and 362 will be disposed in and in electrical contact with the right ventricle 12 of the heart 10.

10 The second lead 354 includes a second elongated, large surface area, electrode 364. When the lead 354 is fed into the superior vena cava 20 and into the coronary sinus 22 through the right atrium 16 as illustrated, the second elongated electrode 364 will be disposed within the coronary sinus just beneath the left atrium 18 and adjacent to the left ventricle 14. Since the coronary sinus 22 is in close proximity to the left atrium 18, 15 electrode 364 will be in electrical contact with the left atrium 18. To assist in fixing lead 354 in place against blood flow, the lead 354 is provided with a preformed bend at 355 as described with respect to previous embodiments.

20 The first lead 352 carries or includes a first elongated, large surface area, electrode 366. The lead 352 is fed into the superior vena cava 20 and into the right atrium 16. The lead 352, in the region of the electrode 366, has a preformed upturn to form a "j" so that the first elongated electrode 366 is disposed within 25 and in electrical contact with the right atrium 16 and more specifically within the right atrial appendage 17.

30 The lead system 350 may be utilized to advantage in association with the atrial defibrillator 30 illustrated in Figure 1 for monitoring the activity of the heart 10 and for delivering cardioverting or defibrillating electrical energy to the atria 16 and 18 of the heart 10. To that end, the first elongated electrode 366 may be coupled to input 54a of sense amplifier 54 and to output 112a of the discharge circuit 112. The second 35 elongated electrode 364 may be coupled to input 54b of sense amplifier 54 and to output 112b of discharge circuit 112. With such coupling, electrodes 364 and 366 may be utilized for sensing atrial activity of the heart in

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association with sense amplifier 54. Also, the cardioverting electrical energy provided from the charger and storage capacitor 110 and the discharge circuit 112 will be received by electrodes 366 and 364 for applying 5 the electrical cardioverting energy between the right atrium 16 and the coronary sinus 22 beneath the left atrium 18 and adjacent to the left ventricle 14 to deliver the cardioverting electrical energy to the atria 16 and 18 of the heart 10. By virtue of the locations of the 10 elongated stimulating electrodes 354 and 366, the electrical energy applied to the right ventricle 12 and left ventricle 14 when the atria are cardioverted or defibrillated will be minimized.

For sensing electrical activations of the heart, 15 a first pair of the sensing electrodes 358 and 360 carried by the third lead 356 may be coupled to inputs 50b and 50a respectively of sense amplifier 50 and a second pair of the sensing electrodes 360 and 362 of the third lead 356 may be coupled to inputs 52b and 52a respectively of sense 20 amplifier 52. This permits sensing of electrical activations of the heart and more specifically electrical activations at two different areas of the right ventricle 12. This enables the non-coincident sensing of the depolarization activation waves as previously described 25 for synchronizing the delivery of the cardioverting or defibrillating electrical energy to the atria 16 and 18 in synchronism with a detected electrical activation of the heart.

Referring now to Figure 15, it illustrates, in 30 perspective view, a human heart 10 having a lead system 370, configured in accordance with a seventh lead system preferred embodiment of the present invention, implanted therein. The portions of the heart 10 particularly noted in Figure 15 are the right ventricle 12, the left ventricle 14, the right atrium 16, the right atrial appendage 17, the left atrium 18, the superior vena cava 20, the left pulmonary artery 21, and the inferior vena cava 27.

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The lead system 370 generally includes a first lead 372, a second lead 374, and a third lead 376. The leads 372, 374, and 376 are flexible but preformed so that the leads 372, 374, and 376 may be readily fed into the heart 10 and assume the configurations when implanted as illustrated in the Figure.

The third lead 376 carries or includes a first tip or distal sense electrode 378, a second medial sense electrode 380, and a third proximal sense electrode 382. The electrodes 378, 380, and 382 are spaced apart on the lead 376 so that when lead 376 is fed into the superior vena cava 20 and into the right ventricle 12 through the right atrium 16 to a position where electrode 378 is at the apex of the right ventricle, all three sense electrodes 378, 380, and 382 will be disposed in and in electrical contact with the right ventricle 12 of the heart 10.

The second lead 374 includes a second elongated, large surface area, electrode 384. When the lead 374 is fed into the superior vena cava 20 and into the left pulmonary artery 21 through the right atrium 16 and right ventricle 12 as illustrated, the second elongated electrode 384 will be disposed within the left pulmonary artery 21 adjacent to the left atrium 18. Since the left pulmonary artery 21 is in close proximity to the left atrium 18, electrode 384 will be in electrical contact with the left atrium 18. Also, to assist in fixing lead 374 in place, lead 374 is provided with a preformed bend at 375 where the lead 374 enters the right ventricle 12 from the right atrium 16.

The first lead 372 carries or includes a first elongated, large surface area, electrode 386. The lead 372 is fed into the superior vena cava 20 and in the right atrium 16. The lead 372, in the region of the electrode 386, is upturned to form a "j" so that the first elongated electrode 386 is disposed within and in electrical contact with the right atrium 16 and more specifically within the right atrial appendage 17.

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The lead system 370 may be utilized to advantage in association with the atrial defibrillator 30 illustrated in Figure 1 for monitoring the activity of the heart 10 and for delivering cardioverting or 5 defibrillating electrical energy to the atria 16 and 18 of the heart 10. To that end, the first elongated electrode 386 may be coupled to input 54a of sense amplifier 54 and to output 112a of the discharge circuit 112. The second elongated electrode 284 may be coupled to input 54b of 10 sense amplifier 54 and to output 112b of discharge circuit 112. With such coupling, electrodes 384 and 386 may be utilized for sensing atrial activity of the heart in association with sense amplifier 54. Also, the cardioverting electrical energy provided from the charger 15 and storage capacitor 110 and the discharge circuit 112 will be received by electrodes 386 and 384 for applying the electrical cardioverting energy between the right atrium 16 and the left pulmonary artery 21 adjacent to the left atrium 18 to deliver the cardioverting electrical 20 energy to the atria 16 and 18 of the heart 10. By virtue of the locations of the elongated stimulating electrodes 386 and 384, the electrical energy applied to the right ventricle 12 and left ventricle 14 when the atria are cardioverted or defibrillated will be minimized.

25 For sensing electrical activations of the heart, a first pair of the sensing electrodes 378 and 380 carried by the third lead 376 may be coupled to inputs 50b and 50a respectively of sense amplifier 50 and a second pair of the sensing electrodes 380 and 382 of the third lead 376 30 may be coupled to inputs 52b and 52a respectively of sense amplifier 52. This permits sensing of electrical activations of the heart and more specifically electrical activations at two different areas of the right ventricle 12. This enables the non-coincident sensing of the 35 depolarization activation waves as previously described for synchronizing the delivery of the cardioverting or defibrillating electrical energy to the atria 16 and 18 in

synchronism with a detected electrical activation of the heart.

Referring now to Figure 16, it illustrates, in perspective view, a human heart 10 having a lead system 390, configured in accordance with an eighth lead system preferred embodiment of the present invention, implanted wherein. The portions of the heart 10 particularly noted in Figure 12 are the right ventricle 12, the left ventricle 14, the right atrium 16, the right atrial appendage 17, the left atrium 18, the superior vena cava 20, the coronary sinus 22, the great vein 23, and the inferior vena cava 27.

The lead system 310 generally includes a first lead 392 and a second lead 394. The leads 392 and 394 are flexible but preformed so that the leads 392 and 394 may be readily fed into the heart 10 and assume the configurations when implanted as illustrated in the Figure.

The second lead 394 carries or includes a first tip or distal sense electrode 396 and a second medial sense electrode 398. The electrodes 396 and 398 are spaced apart on the lead 394 so that when lead 394 is fed into the superior vena cava 20 and into the right ventricle 12 through the right atrium 16 to a position where electrode 396 is at the apex of the right ventricle, the electrodes 396 and 398 will be disposed in and in electrical contact with the right ventricle 12 of the heart 10.

The first lead 392 includes a first elongated, large surface area, electrode 402 and a second elongated, large surface area, electrode 404. The electrodes 402 and 404 are spaced apart on the first lead 392 so that when the lead 392 is fed into the superior vena cava 20 and into the coronary sinus 22 as illustrated through the right atrium 16 with the second elongated electrode 404 disposed within the coronary sinus 22 just beneath the left atrium 18 and adjacent to the left ventricle 14, the first elongated electrode 402 will be disposed in and in

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electrical contact with the right atrium 16. Since the coronary sinus 22 is in close proximity to the left atrium 18, electrode 404 will be in electrical contact with the left atrium 18.

5 It will be noted that the lead 392 is looped or pigtailed in the right atrium 16 so that the first electrode 402 is disposed in the right atrial appendage 17. To assist in assuring that electrode 402 is in the right atrial appendage 17, the lead 392 is provided with  
10 a first preformed bend at 393 in the area where lead 392 enters the right atrium 16 from the superior vena cava 20 and a stiffened section 395 to force the electrode 402 against the inner wall of the right atrium 16 in the right atrial appendage 17. The lead 12 is further provided with  
15 a second preformed bend at 397 to assist in fixing lead 392 in place against blood flow in the coronary sinus 22.

The lead system 390 may be utilized to advantage in association with the atrial defibrillator 30 illustrated in Figure 1 for monitoring the activity of the heart 10 and for delivering cardioverting or defibrillating electrical energy to the atria 16 and 18 of the heart 10. To that end, the first elongated electrode 402 may be coupled to input 54a of sense amplifier 54 and to output 112a of the discharge circuit 112. The second elongated electrode 404 may be coupled to input 54b of sense amplifier 54 and to output 112b of discharge circuit 112. With such coupling, electrodes 402 and 404 may be utilized for sensing atrial activity of the heart in association with sense amplifier 54. Also, the cardioverting electrical energy provided from the charger and storage capacitor 110 and the discharge circuit 112 will be received by electrodes 402 and 404 for applying the electrical cardioverting energy between the right atrium 16 and the coronary sinus 22 beneath the left atrium 18 and adjacent to the left ventricle 14 to deliver the cardioverting electrical energy to the atria 16 and 18 of the heart 10. By virtue of the locations of the elongated stimulating electrodes 402 and 404, the

electrical energy applied to the right ventricle 12 and left ventricle 14 when the atria are cardioverted or defibrillated will be minimized.

For sensing electrical activations of the heart, 5 the sensing electrodes 396 and 398 carried by the second lead 394 may be coupled to inputs 50b and 50a respectively of sense amplifier 50 and electrodes 404 and 396 may be coupled to inputs 52b and 52a respectively of sense amplifier 52. This permits sensing of electrical 10 activations of the heart and more specifically electrical activations at two different areas of the heart 10. This enables the non-coincident sensing of the depolarization activation waves as previously described for synchronizing the delivery of the cardioverting or defibrillating 15 electrical energy to the atria 16 and 18 in synchronism with a detected electrical activation of the heart.

As previously mentioned, and in accordance with the preferred embodiments of the present invention, the paths for applying the cardioverting or defibrillating 20 electrode energy to the atria are between the right atrium and the coronary sinus beneath the left atrium and between the right atrium and the left pulmonary artery adjacent the left atrium. The applied cardioverting or defibrillating electrical energy preferably has a biphasic 25 waveform wherein the energy is of one polarity during a first time period or phase and of opposite polarity during an immediately succeeding second time period or phase. Preferably the first and second time periods are of equal duration, of for example, two to four milliseconds. Also, 30 for the right atrium to coronary sinus path, the total quantity of applied electrical energy is preferably between .5 and 2.1 joules. For the right atrium to pulmonary artery path, the total quantity of applied electrical energy is preferably between 1.0 and 5.5 35 joules. Pulse generators for generating such biphasic electrical energy waveforms are well known in the art.

These energy levels are much lower than the energy levels utilized for the ventricular defibrillation

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and the energy level previously thought necessary for atrial defibrillation. It is believed that these relatively low energy levels are obtainable because the lead systems disclosed herein place the most fibrillation 5 atrial tissue between the electrodes which apply the cardioverting or defibrillating electrical energy.

The foregoing electrode placement which results in lower required applied energy has a number of advantages. First and foremost, the lower applied 10 energies result in less discomfort to the patient when applied. Second, because less battery power is consumed during cardioversion or defibrillation, the implanted atrial defibrillator will have a longer useful life requiring less frequent defibrillator replacement. Third, 15 the energy is concentrated on the atria and hence less energy is received by the ventricles reducing the risk of inducing ventricular fibrillation.

From the foregoing, it can be seen that the present invention provides a new and improved fully 20 implantable atrial defibrillator which is fully automatic. In addition, the atrial defibrillator of the present invention is arranged to conserve power to minimize the frequency in which a depletable power source must be replaced. In addition, the atrial defibrillator of the 25 present invention assures reliable synchronizing of the defibrillating or cardioverting electrical energy to the atria with sensed electrical activations in the heart. Further, the atrial defibrillator of the present invention provides a means by which the reliable generation of 30 synchronizing pulses may be confirmed. All of the foregoing assures that an atrial defibrillator is provided which is safe in use and has an extended lifetime.

While a particular embodiment of the present invention has been shown and described, modifications may 35 be made, and it is therefore intended in the appended claims to cover all such changes and modifications which fall within the true spirit and scope of the invention.

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What is claimed is:

1. An atrial defibrillator for applying an electrical defibrillating pulse to the atria of a human heart, said atrial defibrillator being arranged to apply said electrical defibrillating pulse to the atria in synchronism with depolarization activation waves and comprising:

first means for sensing depolarization activation waves at a first area of the heart;

second means for sensing said depolarization activation waves at a second area of the heart;

means for detecting non-coincident sensing of said depolarization activation waves at said first area of the heart by said first means and at said second area of the heart by said second means;

storage means for storing electrical energy; and

delivery means coupled to said storage means and being responsive to the non-coincident sensing of a depolarization activation wave at said first and second areas of the heart for applying a predetermined amount of said stored electrical energy to the atria.

2. An atrial defibrillator as defined in claim 1 wherein said means for detecting includes delay establishing means for establishing a range of normal delay times between a depolarization activation wave being sensed at said first area of the heart by said first means and being sensed at said second area of the heart by said second means, and wherein said delivery means is responsive to the sensing of a depolarization activation wave at said first and second areas of the heart within said range of normal delay times for applying a predetermined amount of said stored electrical energy to the atria.

3. An atrial defibrillator as defined in claim 2 wherein said first means include first lead means

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arranged for establishing electrical contact with the right ventricle of the heart for sensing said depolarization activation waves at the right ventricle and 5 wherein said second means include second lead means arranged for establishing electrical contact with the left ventricle of the heart for sensing said depolarization activation waves at the left ventricle of the heart.

4. An atrial defibrillator as defined in claim 3 where said range of normal delay times is between five milliseconds and thirty milliseconds.

5. An atrial defibrillator as defined in claim 3 wherein said first lead means comprises an endocardial lead and said second lead means comprises an intravascular lead.

6. An atrial defibrillator as defined in claim 2 wherein said delivery means include timer means, said timer means being arranged to begin the keeping of time responsive to a depolarization activation wave being sensed by said first means and to terminate the keeping of 5 time responsive to said depolarization activation wave being sensed by said second means.

7. An atrial defibrillator as defined in claim 6 wherein said delivery means further include means for comparing the time kept by said timer means to said range of normal delay times.

8. An atrial defibrillator as defined in claim 7 wherein said delivery means further includes synchronizing pulse generating means for generating a synchronizing pulse responsive to said comparing means when the time kept by said timer means is within said 5 range of normal delay times.

9. An atrial defibrillator as defined in claim 8 wherein said delivery means further includes counter means for counting said synchronizing pulses and is further arranged for applying said electrical energy to the atria when a predetermined number of said 5 synchronizing pulses have been counted.

10. An atrial defibrillator as defined in claim 9 wherein said comparing means is arranged to reset said counter means when the time kept by said timer means is outside said range of normal delay times.

11. An atrial defibrillator as defined in claim  
9 wherein said predetermined number is five.

12. An implantable atrial cardioverter arranged to be powered by a depletable power source for delivering electrical energy to the atria of a human heart in need of cardioversion, said atrial cardioverter comprising:

means responsive to said sensing means for determining the time intervals between said sensed electrical activations;

enable means for enabling said atrial arrhythmia detector means responsive to said determined time intervals; and

20 delivery means responsive to said atrial arrhythmia detector means for delivering said electrical energy to the atria of the heart in response to said atrial arrhythmia detector means detecting atrial arrhythmia of the heart.

13. An atrial cardioverter as defined in claim  
12 wherein said enable means include averaging means for  
determining the average time interval of the last  
predetermined number of determined time intervals  
responsive to each sensed electrical activation and where  
said enable means are arranged to enable said atrial  
arrythmia detector means when one of said average time  
intervals is less than a predetermined time interval.

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14. An atrial cardioverter as defined in claim 13 wherein said predetermined time interval is 500 milliseconds.

15. An atrial cardioverter as defined in claim 13 when said predetermined number of determined time intervals is equal to twenty.

16. An atrial cardioverter as defined in claim 12 wherein said atrial cardioverter is an atrial defibrillator and wherein said atrial arrhythmia detector means is an atrial fibrillation detector means for detecting the presence of atrial fibrillation of the heart.

17. An atrial defibrillator as defined in claim 17 wherein said enable means include time interval variation determining means for determining the variation in the time intervals of the last predetermined number of 5 determined time intervals responsive to each sensed electrical activation and wherein said enable means are arranged to enable said atrial fibrillation detector means when one of said variations exceeds a predetermined variation.

18. An atrial defibrillator as defined in claim 17 wherein said variation determining means comprises a standard deviation determining means.

19. An atrial defibrillator as defined in claim 18 wherein said predetermined variation is a standard deviation equal to twenty milliseconds.

20. An atrial defibrillator as defined in claim 18 wherein said predetermined number of determined time intervals is equal to twenty.

21. An atrial defibrillator as defined in claim 16 wherein said enable means comprises averaging means for determining the average time interval of the last predetermined number of determined time intervals 5 responsive to each sensed electrical activation and standard deviation determining means for determining the standard deviation in the time intervals of said last predetermined number of determined time intervals

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10 responsive to each sensed electrical activation and wherein said enable means are arranged to enable said atrial fibrillation detector means when one of said average time intervals is less than a predetermined time interval and when the corresponding standard deviation exceeds a predetermined standard deviation.

22. An atrial defibrillator as defined in claim 21 wherein said predetermined number of determined time intervals is equal to twenty.

23. An atrial defibrillator as defined in claim 21 wherein said predetermined time interval is 500 milliseconds and said predetermined standard deviation is twenty milliseconds.

24. An atrial defibrillator as defined in claim 16 further including storing means for storing said determined time intervals.

25. An atrial defibrillator as defined in claim 24 wherein said enable means are arranged for enabling said atrial fibrillation detector means responsive to the average of said stored time intervals.

26. An atrial defibrillator as defined in claim 25 wherein said enable means are arranged for enabling said atrial fibrillation detector means also responsive to the standard deviation of said stored time intervals.

27. An atrial defibrillator as defined in claim 26 wherein said stored time intervals comprises the last predetermined number of determined time intervals.

28. An atrial defibrillator as defined in claim 16 wherein said sensing means include lead means arranged to establish electrical contact with the right ventricle of the heart for sensing electrical activation in the right ventricle of the heart.

29. An atrial defibrillator as defined in claim 16 further including disable means for disabling said atrial fibrillation detector means when said atrial fibrillator detector means has been enabled for a predetermined time period and has failed to detect the presence of atrial fibrillation of the heart.

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30. An atrial defibrillator as defined in claim 29 wherein said disable means includes a timer for timing said predetermined time period.

31. An atrial defibrillator as defined in claim 16 further including atrial sense means coupled to said atrial fibrillation detector means for sensing atrial activity of the heart and wherein said enable means are arranged for enabling said atrial sense means upon enabling said atrial fibrillation detector means.

32. An atrial defibrillator arranged to be implanted beneath the skin of a patient for applying electrical energy to the atria of a human heart, said atrial defibrillator comprising:

first delivery means for delivering a first quantity of electrical energy to the atria of the heart in synchronism with one of said sensed electrical activations for cardioverting the atria;

15 second delivery means for delivering at least one pulse of electrical energy to the heart in synchronism with one of said sensed electrical activations, said pulse of electrical energy being of insufficient quantity to cardiovert the heart but of sufficient quantity so as to be detected on an electrocardiogram generated externally to the skin of the patient; and

select means for selecting either said first delivery means or said second delivery means.

33. An atrial defibrillator as defined in claim 32 wherein said second delivery means are arranged to deliver said pulse of electrical energy to the right ventricle of the heart.

34. An atrial defibrillator as defined in claim 32 wherein said sensing means includes lead means arranged to establish electrical contact with the right ventricle of the heart for sensing said electrical activations in the right ventricle of the heart.

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35. An atrial defibrillator as defined in claim 34 wherein said second delivery means are arranged to deliver said pulse of electrical energy to the right ventricle through said lead means.

36. An atrial defibrillator as defined in claim 32 wherein said second delivery means are arranged to deliver a plurality of said pulses of electrical energy, each said pulse being delivered in succession in synchronism with successive sensed electrical activations.

37. An atrial defibrillator as defined in claim 36 wherein said second delivery means includes terminating means for terminating the delivery of said pulses after a predetermined number of said pulses have been delivered to the heart.

38. An atrial defibrillator as defined in claim 37 wherein said terminating means include a counter for counting said delivered pulses and means for comprising said counted pulses to said predetermined number.

39. An atrial defibrillator as defined in claim 38 wherein said predetermined number is sixty.

40. An atrial defibrillator as defined in claim 32 wherein said first delivery means include lead means arranged to deliver said first quantity of electrical energy from one atrium of the heart to the other atrium of the heart.

41. An atrial defibrillator as defined in claim 32 wherein said first quantity of electrical energy is in the range of .1 to 3 joules and wherein said pulse of electrical energy has a quantity in the range of 5 to 50 microjoules.

42. An atrial defibrillator as defined in claim 32 further including means for generating a synchronizing pulse for each sensed electrical activation and enable means for activating the selected one of said first or second delivery means in response to the generating of said synchronizing pulses.

43. An atrial defibrillator for applying an electrical defibrillating pulse to the atria of a human

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heart in synchronism with an electrical activation of the heart. said atrial defibrillator comprising:

5 sensing means for sensing electrical activations of the heart;

synchronizing pulse generating means responsive to said sensing means for generating a synchronizing pulse for each said sensed electrical activation;

10 activation; counting means for counting said synchronizing pulses provided by said synchronizing pulse generating means; and

15 delivery means responsive to said counting means for applying said electrical defibrillating pulse to the atria after a predetermined number of said synchronizing pulses have been counted by said counter means and in response to the last one of said predetermined number of synchronizing pulses.

44. An atrial defibrillator as defined in claim  
43 wherein said predetermined number is five.

45. An atrial defibrillator as defined in claim 43 wherein said sensing means include lead means arranged to establish electrical contact with the right ventricle of the heart for sensing said electrical activations in the right ventricle.

46. An atrial defibrillator as defined in claim  
43 wherein said sensing means include first means for  
sensing said electrical activations at a first area of the  
heart and second means for sensing said electrical  
activations at a second area of the heart, wherein said  
atrial defibrillator further comprises delay establishing  
means for establishing a range of normal delay times  
between an electrical activation being sensed at said  
first area of the heart by said first means and being  
sensed at said second area of the heart by said second  
means and wherein said synchronizing pulse generating  
means is responsive to the sensing of an electrical  
activation at said first and second areas of the heart

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15        within said range of normal delay times for generating  
each said synchronizing pulse.

47. An atrial defibrillator as defined in claim  
46 wherein said first means include first lead means  
arranged for establishing electrical contact with the  
right ventricle of the heart for sensing said electrical  
5        activations at the right ventricle and wherein said second  
means include second lead means arranged for establishing  
electrical contact with the left ventricle of the heart  
for sensing said electrical activations at the left  
ventricle of the heart.

48. An atrial defibrillator as defined in claim  
47 where said range of normal delay times is between five  
milliseconds and thirty milliseconds.

49. An atrial defibrillator as defined in claim  
46 further including timer means arranged to begin the  
keeping of time responsive to an electrical activation  
being sensed by said first means and to terminate the  
5        keeping of time responsive to said electrical activation  
being sensed by said second means.

50. An atrial defibrillator as defined in claim  
49 further including means for comparing the time kept by  
said timer means to said range of normal delay times.

51. An atrial defibrillator as defined in claim  
50 wherein said synchronizing pulse generating means is  
responsive to said comparing means for generating a  
synchronizing pulse when the time kept by said timer means  
is within said range of normal delay times.

52. An atrial defibrillator as defined in claim  
51 wherein said comparing means is arranged to reset said  
counter means when the time kept by said timer means is  
outside said range of normal delay times.

53. An atrial defibrillator as defined in claim  
52 wherein said predetermined number is five.

54. A lead for use in association with an  
atrial defibrillator of the type arranged to cardiovert  
the atria of the human heart, said lead comprising:

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55. A lead as defined in claim 54 wherein said conductor means are coaxially disposed with said first conductor being a center conductor, said second conductor being an inner conductor, and said third conductor forming an outer conductor.

56. A lead as defined claim 54 wherein the distal end beyond said third electrode is preshaped to generally conform to the shape of the coronary sinus of the heart.

57. An implantable atrial defibrillator for applying an electrical defibrillating pulse to the atria of a human heart, said atrial defibrillator comprising:

5 first means for sensing electrical activations of the heart at the right ventricle;

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second means for sensing electrical activations of the heart at the left ventricle;

10 enable means responsive to said first means for detecting an abnormal rhythm of the right ventricle and providing an enable control signal;

15 atrial fibrillation detector means including atrial sensing means for sensing atrial activity of at least one of the atria, said atrial fibrillation detector means being arranged to be activated by said enable control signal for detecting atrial fibrillation of the heart;

storage means for storing electrical energy responsive to said atrial fibrillation detector means detecting atrial fibrillation; and

20 delivery means responsive to said atrial fibrillation detector means, coupled to said storage means, and being responsive to non-coincident sensing of an electrical activation by said first and second means for applying a predetermined amount of said stored electrical energy to the atria of the heart.

25 58. An atrial defibrillator as defined in claim 57 wherein said enable means comprises means for determining the time intervals between said electrical activations sensed by said first means, averaging means for determining the average time interval of the last predetermined number of determined time intervals responsive to each sensed electrical activation and standard deviation determining means for determining the standard deviation in the time intervals of said last predetermined number of determined time intervals 10 responsive to each sensed electrical activation and wherein said enable means are arranged to provide said enable control signal to said atrial fibrillation detector means when one of said average time intervals is less than a predetermined time interval and when the corresponding 15 standard deviation exceeds a predetermined standard deviation.

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59. An atrial defibrillator as defined in claim 58 wherein said predetermined number of determined time intervals is equal to twenty.

60. An atrial defibrillator as defined in claim 58 wherein said predetermined time interval is 500 milliseconds and said predetermined standard deviation is twenty milliseconds.

61. An atrial defibrillator as defined in claim 57 further including delay establishing means for establishing a range of normal delay times between an electrical activation being sensed at the right ventricle 5 of the heart by said first means and being sensed at the left ventricle of the heart by said second means, and wherein said delivery means is responsive to the sensing of an electrical activation by said first and second means within said range of normal delay times for applying said 10 predetermined amount of said stored electrical energy to the atria.

62. An atrial defibrillator as defined in claim 61 where said range of normal delay times is between five milliseconds and thirty milliseconds.

63. An atrial defibrillator as defined in claim 61 wherein said delivery means further includes synchronizing pulse generating means for generating a synchronizing pulse when said first and second means sense 5 an electrical activation within said range of normal delay times.

64. An atrial defibrillator as defined in claim 62 wherein said delivery means further includes counter means for counting said synchronizing pulses and is further arranged for applying said electrical energy to the atria when a predetermined number of said 5 synchronizing pulses have been counted.

65. An atrial defibrillator as defined in claim 63 wherein said predetermined number is five.

66. An atrial defibrillator as defined in claim 61 further comprising second delivery means for delivering at least one pulse of electrical energy to the heart in

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5 response to one of said synchronizing pulses, said pulse of electrical energy being of insufficient quantity to cardiovert the heart so as to be detected on an electrocardiogram generated externally to the skin of the patient and select means for selecting either said first delivery means or said second delivery means.

67. An atrial defibrillator as defined in claim 66 wherein said second delivery means are arranged to deliver said pulse of electrical energy to the right ventricle of the heart.

68. An atrial defibrillator as defined in claim 66 wherein said second delivery means are arranged to deliver a plurality of said pulses of electrical energy, each said pulse being delivered in succession in response to successive synchronizing pulses.

69. An atrial defibrillator as defined in claim 68 wherein said second delivery means includes terminating means for terminating the delivery of said pulses after a predetermined number of said pulses have been delivered to the heart.

70. An atrial defibrillator as defined in claim 69 wherein said predetermined number is sixty.

71. A method of applying electrical defibrillating energy to the atria of a human heart while minimizing the electrical energy applied to the right and left ventricles, said method comprising the steps of:

5 providing a first electrode;  
establishing electrical contact between said first electrode and a point within the coronary sinus beneath the left atrium;

10 providing a second electrode;  
establishing electrical contact between said second electrode and a region adjacent to the right atrium; and

applying defibrillating electrical energy between said first and said second electrodes.

72. A method as defined in claim 71 wherein second establishing step includes establishing electrical

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contact between said second electrode and the interior of the superior vena cava above the right atrium opening to the coronary sinus.

73. A method as defined in claim 71 including the further step of sensing electrical activations of the heart and wherein said applying step is performed during a sensed electrical activation.

74. A method as defined in claim 73 wherein said sensing step is performed by sensing an electrical activation at first and second areas of the heart and wherein said applying step is performed when the sensing of the electrical activation at the first and second areas of the heart is non-coincident.

75. A method as defined in claim 74 including the further step of establishing a range of normal delay times between the sensing of an electrical activation at the first and second areas of the heart and wherein said applying step is performed upon the sensing of an electrical activation at the first and second areas of the heart within said range of normal delay times.

76. A method as defined in claim 75 wherein said first area of the heart is the right ventricle and wherein said second area of the heart is the left ventricle.

77. A method as defined in claim 71 wherein said first and second electrodes are provided on a single lead and wherein said method includes the further step of passing said lead down the superior vena cava of the heart, into the right atrium, into the coronary sinus ostium, and into the coronary sinus of the heart near the left side thereof, and wherein said electrodes are spaced apart such that when said first electrode is beneath the left atrium near the left ventricle, said second electrode is within the right atrium or the superior vena cava.

78. A lead system for use with an implantable device for monitoring activity of the heart and delivering cardioverting electrical energy to the atria of the heart,

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5 said device including storage means for storing said electrical energy, said lead system comprising:

10 lead means coupled to said storage means for receiving said electrical energy from said storage means and applying said electrical energy between the right atrium of the heart and at least one of the coronary sinus beneath the left atrium of the heart and the left pulmonary artery adjacent the left atrium of the heart for delivering said electrical energy to the atria of the heart; and

15 said lead means being fully implantable beneath the skin of a patient.

79. A lead system as defined in claim 78 wherein said lead means includes a first electrode arranged to be disposed within the right atrium of the heart and a second electrode arranged to be disposed within the coronary sinus beneath the left atrium of the heart for delivering said electrical energy to the atria of the heart.

5 80. A lead system as defined in claim 79 wherein said lead means comprises a first lead including said first electrode and a second lead including said second electrode.

81. A lead system as defined in claim 80 wherein said first electrode is further arranged for being disposed in the right atrial appendage of the heart.

82. A lead system as defined in claim 80 wherein said device further includes atrial activity sensing means for sensing atrial activity of the heart, and wherein said atrial activity sensing means is coupled to said first and second electrodes.

5 83. A lead system as defined in claim 82 wherein said device further includes electrical activation sensing means for sensing electrical activations of the heart and wherein said lead means includes a first pair of spaced apart sensing electrodes carried on said first lead and a second pair of spaced apart sensing electrodes carried on said second lead, said first and second pairs

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of sensing electrodes being coupled to said electrical activation sensing means.

84. A lead system as defined in claim 83 wherein said first pair of sensing electrodes are arranged on said first lead for being disposed within the right ventricle of the heart and wherein said second pair of sensing electrodes are arranged on said second lead for being disposed within coronary vein adjacent to the left ventricle of the heart.

5 85. A lead system as defined in claim 84 wherein said coronary vein is the great vein of the heart.

86. A lead system as defined in claim 84 wherein said second lead includes a preshaped bend for fixing said second lead within said coronary sinus.

87. A lead system as defined in claim 86 wherein said second lead is configured for being advanced through the right atrium of the heart, into the coronary sinus of the heart, and into said coronary vein, and wherein said preshaped bend of said second lead is in a region of said second lead where said second lead extends from the coronary sinus into said coronary vein.

5 88. A lead system as defined in claim 82 wherein said device further includes electrical activation sensing means for sensing electrical activations of the heart and wherein said lead means includes a third lead and first, second, and third spaced apart sensing electrodes carried on said third lead and coupled to said electrical activation sensing means.

89. A lead system as defined in claim 88 wherein said first, second, and third spaced apart sensing electrodes are arranged on said third lead for being disposed within the right ventricle of the heart.

90. A lead system as defined in claim 89 wherein said first electrode is further arranged for being disposed in the right atrial appendage of the heart.

91. A lead system as defined in claim 90 wherein said second lead includes a preshaped bend in the

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region of said second lead within the coronary sinus for fixing said second lead within the coronary sinus.

92. A lead system as defined in claim 79 wherein said lead means comprises a first lead including said first and second electrodes.

93. A lead system as defined in claim 92 wherein said first lead is configured for being advanced through the right atrium and into the coronary sinus of the heart.

94. A lead system as defined in claim 93 wherein said first lead includes a preshaped bend in the region of said first lead within the coronary sinus for fixing said first lead within the coronary sinus.

95. A lead system as defined in claim 92 wherein said first electrode is further arranged for being disposed in the right atrial appendage of the heart.

96. A lead system as defined in claim 95 wherein said first lead further includes a preshaped portion in the region of said first lead within the right atrium for forcing said first electrode into the right atrial appendage.

97. A lead system as defined in claim 96 wherein said first lead is looped within the right atrium and wherein said first lead further includes a stiffened portion for forcing said first electrode against the inner wall of the right atrium.

98. A lead system as defined in claim 92 wherein said device further includes atrial activity sensing means for sensing atrial activity of the heart, and wherein said atrial activity sensing means is coupled to said first and second electrodes.

99. A lead system as defined in claim 98 wherein said device further includes electrical activation sensing means for sensing electrical activations of the heart and wherein said lead means include a second lead and first, second, and third spaced apart sensing electrodes carried on said second lead and coupled to said electrical activation sensing means.

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100. A lead system as defined in claim 99 wherein said first, second, and third spaced apart sensing electrodes are arranged on said second lead for being disposed within the right ventricle of the heart.

101. A lead system as defined in claim 98 wherein said device further includes electrical activation sensing means for sensing electrical activations of the heart and wherein said lead means include a second lead and first and second spaced apart sensing electrodes 5 carried on said second lead and wherein said first and second sensing electrodes are coupled to said electrical activation sensing means.

102. A lead system as defined in claim 101 wherein said second electrode and one of said first or second sensing electrodes are also coupled to said electrical activation sensing means.

103. A lead system as defined in claim 78 wherein said lead means includes a first electrode arranged to be disposed within the right atrium of the heart and a second electrode arranged to be disposed within the left pulmonary artery adjacent to the left atrium of the heart for delivering said electrical energy 5 to the atria of the heart.

104. A lead system as defined in claim 103 wherein said lead means comprises a first lead including said first and second electrodes.

105. A lead system as defined in claim 104 wherein said first lead is configured to be advanced through the right atrium, into the right ventricle, and through the right ventricle into the left pulmonary artery of the heart.

106. A lead system as defined in claim 105 wherein said first lead includes a preshaped bend in the region of said first lead extending from the right atrium into the right ventricle for fixing said first lead in place.

107. A lead system as defined in claim 104 wherein said device further includes atrial activity

sensing means for sensing atrial activity of the heart, and wherein said atrial activity sensing means is coupled to said first and second electrodes.

108. A lead system as defined in claim 107 wherein said device further includes electrical activation sensing means for sensing electrical activations of the heart and wherein said lead means includes a second lead and first, second, and third spaced apart sensing electrodes carried on said second lead and coupled to said electrical activation sensing means.

5 109. A lead system as defined in claim 108 wherein said first, second, and third spaced apart sensing electrodes are arranged on said second lead for being disposed within the right ventricle of the heart.

110. A lead system as defined in claim 103 wherein said lead means comprises a first lead including said first electrode and a second lead including said second electrode.

111. A lead system as defined in claim 110 wherein said second lead is configured to be advanced through the right atrium, into the right ventricle, and through the right ventricle into the left pulmonary artery of the heart.

112. A lead system as defined in claim 111 wherein said second lead includes a preshaped bend in the region of said second lead extending from the right atrium into the right ventricle for fixing said second lead in place.

113. A lead system as defined in claim 110 wherein said device further includes atrial activity sensing means for sensing atrial activity of the heart, and wherein said atrial activity sensing means is coupled to said first and second electrodes.

114. A lead system as defined in claim 113 wherein said device further includes electrical activation sensing means for sensing electrical activations of the heart and wherein said lead means includes a third lead and first, second, and third spaced apart sensing

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5     electrodes carried on said third lead and coupled to said electrical activation sensing means.

115. A lead system as defined in claim 114 wherein said first, second, and third spaced apart sensing electrodes are arranged on said third lead for being disposed within the right ventricle of the heart.

116. A lead system as defined in claim 115 wherein said first electrode is further arranged for being disposed in the right atrial appendage of the heart.

117. A method of monitoring activity of the heart of a patient and delivering cardioverting electrical energy to the atria of the heart of the patient, said method comprising the steps of:

5                   providing storage means for storing electrical energy;

implanting said storage means beneath the skin of the patient;

providing lead means;

10                  implanting said lead means beneath the skin of the patient;

coupling said lead means to said storage means;

15                  storing said electrical energy in said storage means, and applying, through said lead means, at least a portion of said stored electrical energy between the right atrium of the heart and at least one of the coronary sinus beneath the left atrium of the heart and the left pulmonary artery adjacent the left atrium of the heart to deliver said cardioverting electrical energy to the atria of the heart.

20                  118. A method as defined in claim 117 wherein said lead means implanting step includes disposing a first electrode within the right atrium of the heart and disposing a second electrode within the coronary sinus beneath the left atrium of the heart and wherein said applying step includes applying said electrical energy between said first and second electrodes.

119. A method as defined in claim 118 wherein said lead means providing step includes providing a first lead with said first electrode and providing a second lead with said second electrode.

120. A method as defined in claim 119 including the further step of sensing atrial activity of the heart between said first and second electrodes.

121. A method as defined in claim 120 including the further steps of providing said first lead with a first pair of spaced apart sensing electrodes, providing said second lead with a second pair of spaced apart sensing electrodes, and sensing electrical activations of 5 the heart between each of said first and second pairs of sensing electrodes.

122. A method as defined in claim 121 including the further steps of disposing said first pair of sensing electrodes of said first lead within the right ventricle of the heart and disposing said second pair of sensing 5 electrodes of said second lead within a coronary vein adjacent to the left ventricle of the heart and communicating with the coronary sinus.

123. A method as defined in claim 122 wherein said coronary vein is the great vein of the heart.

124. A method as defined in claim 122 wherein said first electrode is disposed in the right atrial appendage of the heart.

125. A method as defined in claim 120 including the further steps of providing a third lead with first, second, and third spaced apart sensing electrodes.

126. A method as defined in claim 125 including the further steps of disposing said first, second, and third spaced apart sensing electrodes of said third lead within the right ventricle of the heart and sensing 5 electrical activations of the heart with said first, second, and third sensing electrodes in the right ventricle.

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127. A method as defined in claim 126 wherein said first electrode is disposed in the right atrial appendage of the heart.

128. A method as defined in claim 118 wherein said lead means providing step includes providing a first lead with both said first and second electrodes.

129. A method as defined in claim 128 including the further step of sensing atrial activity of the heart between said first and second electrodes.

130. A method as defined in claim 129 including the further step of providing a second lead with first, second, and third spaced apart sensing electrodes.

131. A method as defined in claim 130 including the further step of disposing said first, second, and third spaced apart sensing electrodes of said second lead within the right ventricle of the heart and sensing electrical activations of the heart with said first, second, and third sensing electrodes in the right ventricle.

132. A method as defined in claim 131 wherein said first electrode is disposed in the right atrial appendage of the heart.

133. A method as defined in claim 129 including the further step of providing a second lead with first and second spaced apart sensing electrodes.

134. A method as defined in claim 133 including the further step of disposing said first and second spaced apart sensing electrodes of said second lead within the right ventricle of the heart and sensing electrical activations of the heart with said first and second sensing electrodes in the right ventricle.

135. A method as defined in claim 134 including the further step of sensing said electrical activations of the heart with said second electrode and either said first or second sensing electrodes.

136. A method as defined in claim 135 wherein said first electrode is disposed in the right atrial appendage of the heart.

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137. A method as defined in claim 117 wherein said lead means implanting step includes disposing a first electrode within the right atrium of the heart and disposing a second electrode within the left pulmonary artery adjacent to the left atrium of the heart and wherein said applying step includes applying said electrical energy between said first and second electrodes.

138. A method as defined in claim 137 wherein said lead means providing step includes providing a first lead with both said first and second electrodes.

139. A method as defined in claim 138 including the further step of sensing atrial activity of the heart between said first and second electrodes.

140. A method as defined in claim 139 including the further steps of providing a second lead with first, second, and third spaced apart sensing electrodes.

141. A method as defined in claim 140 including the further steps of disposing said first, second, and third spaced apart sensing electrodes of said second lead within the right ventricle of the heart and sensing electrical activations of the heart with said first, second, and third sensing electrodes in the right ventricle.

142. A method as defined in claim 137 wherein said lead means providing step includes providing a first lead with said first electrode and providing a second lead with said second electrode.

143. A method as defined in claim 142 including the further step of sensing atrial activity of the heart between said first and second electrodes.

144. A method as defined in claim 143 including the further step of providing a third lead with first, second, and third spaced apart sensing electrodes.

145. A method as defined in claim 143 including the further steps of disposing said first, second, and third spaced apart sensing electrodes of said third lead within the right ventricle of the heart and sensing

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5 electrical activations of the heart with said first, second, and third sensing electrodes in the right ventricle.

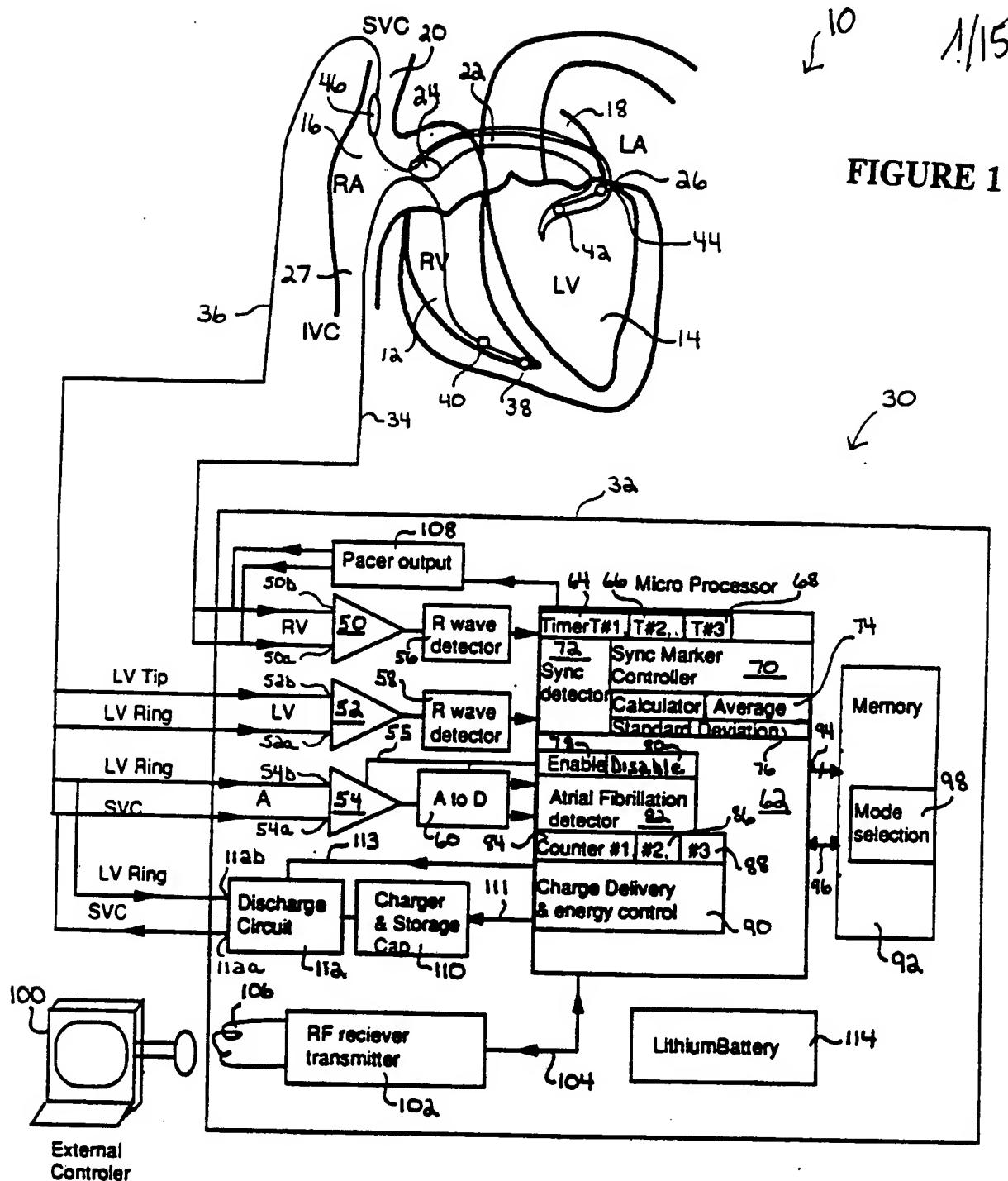
146. A method as defined in claim 145 wherein said first electrode is disposed in the right atrial appendage of the heart.

147. A method as defined in claim 118 wherein said applying step includes applying said electrical energy in the form of a biphasic waveform having a pair of equal duration phases and a total energy between .5 and 2.1 joules.

148. A method as defined in claim 147 wherein each of said phases has a duration between 2 and 4 milliseconds.

149. A method as defined in claim 137 wherein said applying step includes applying said electrical energy in the form of a biphasic waveform having a pair of equal duration phases and a total energy between 1.0 and 5.5 joules.

150. A method as defined in claim 149 wherein each of said phases has a duration between 2 and 4 milliseconds.



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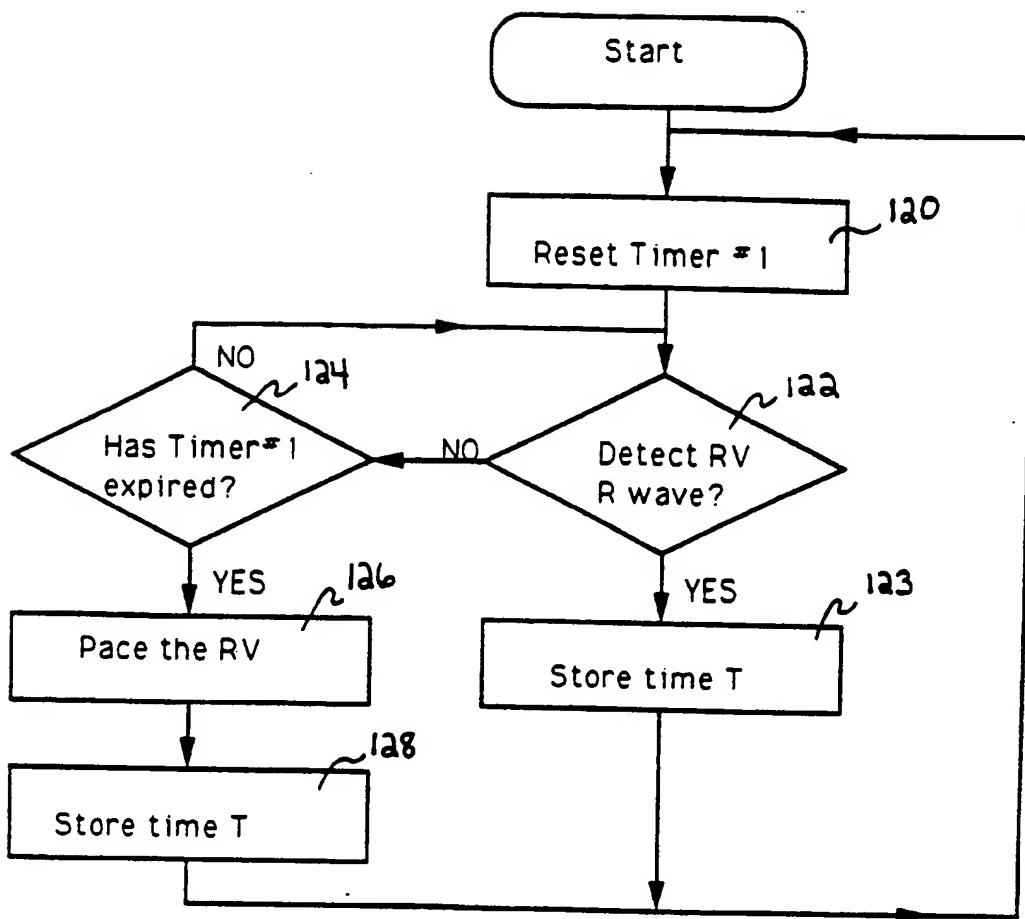
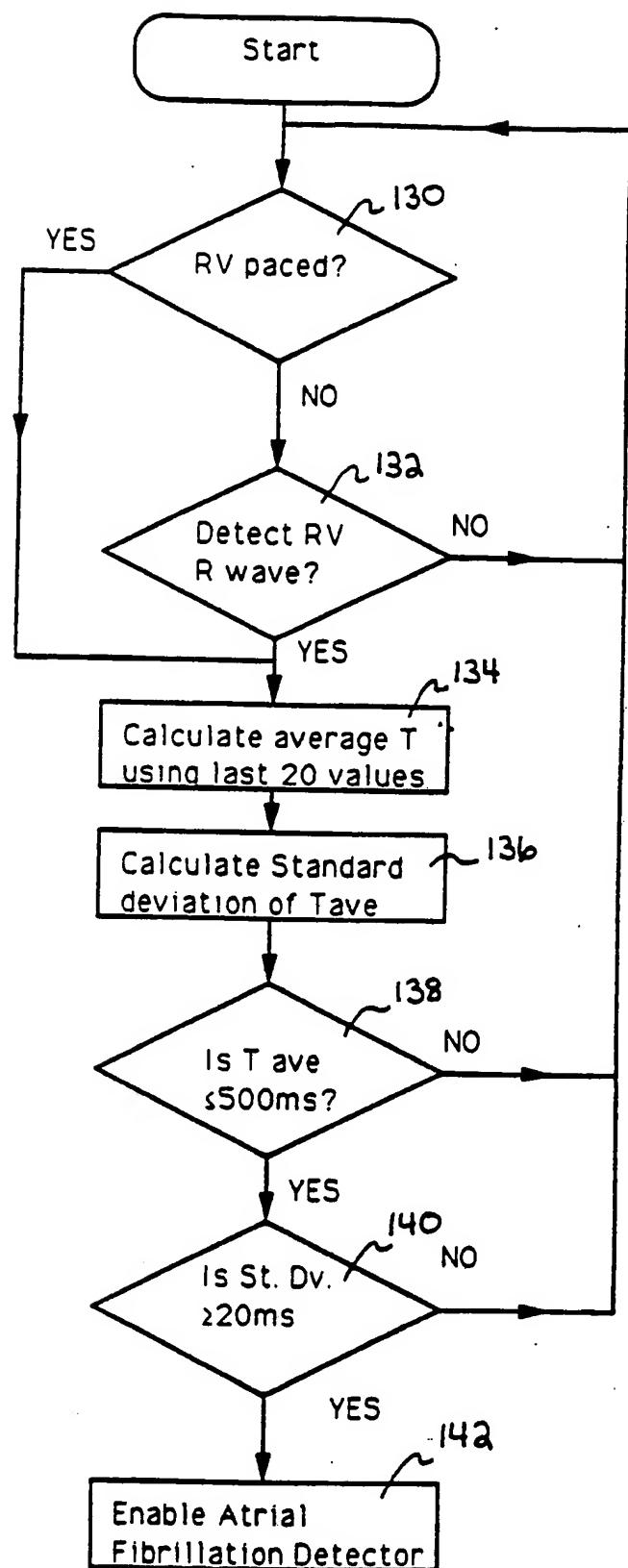
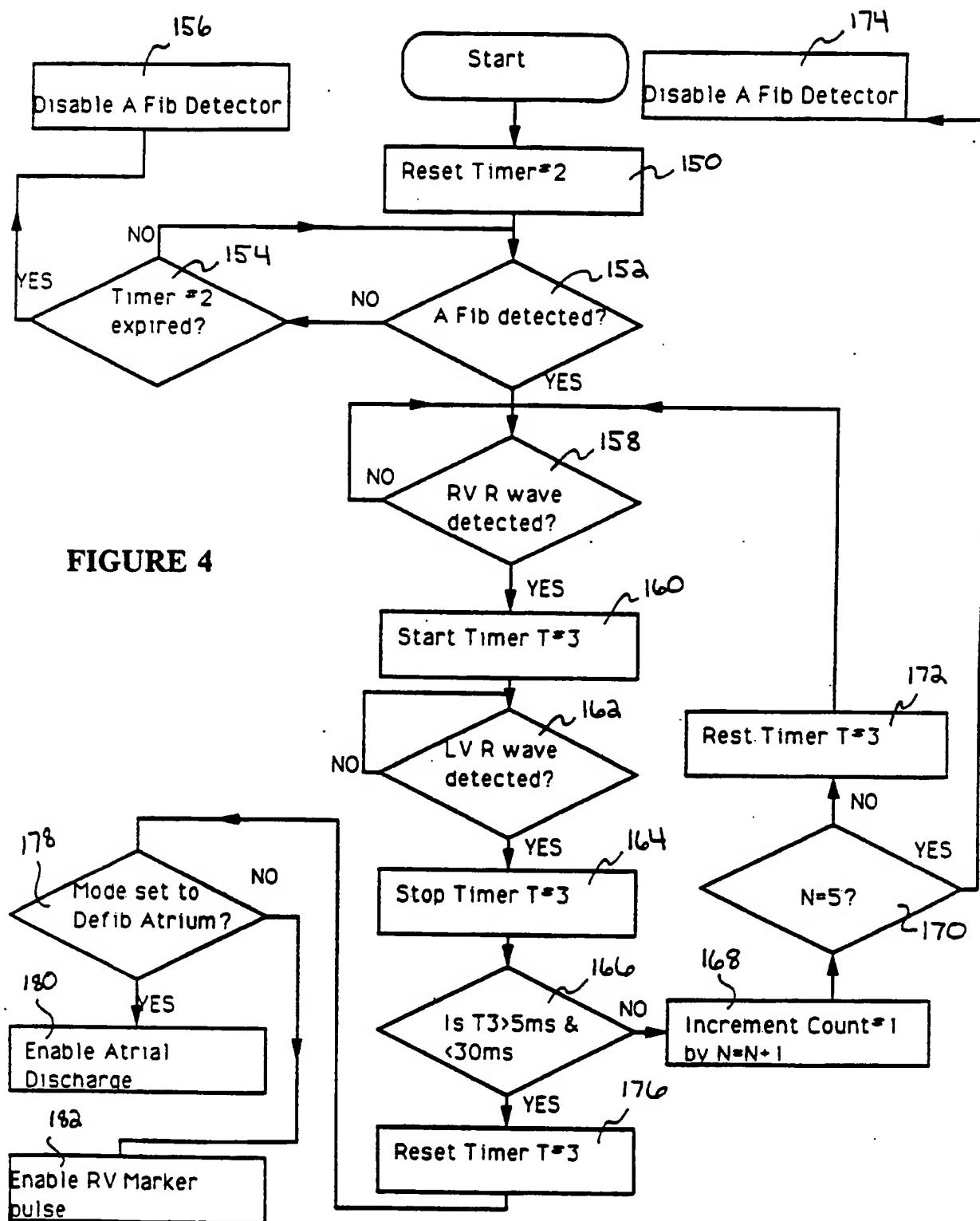


FIGURE 2

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**FIGURE 3**

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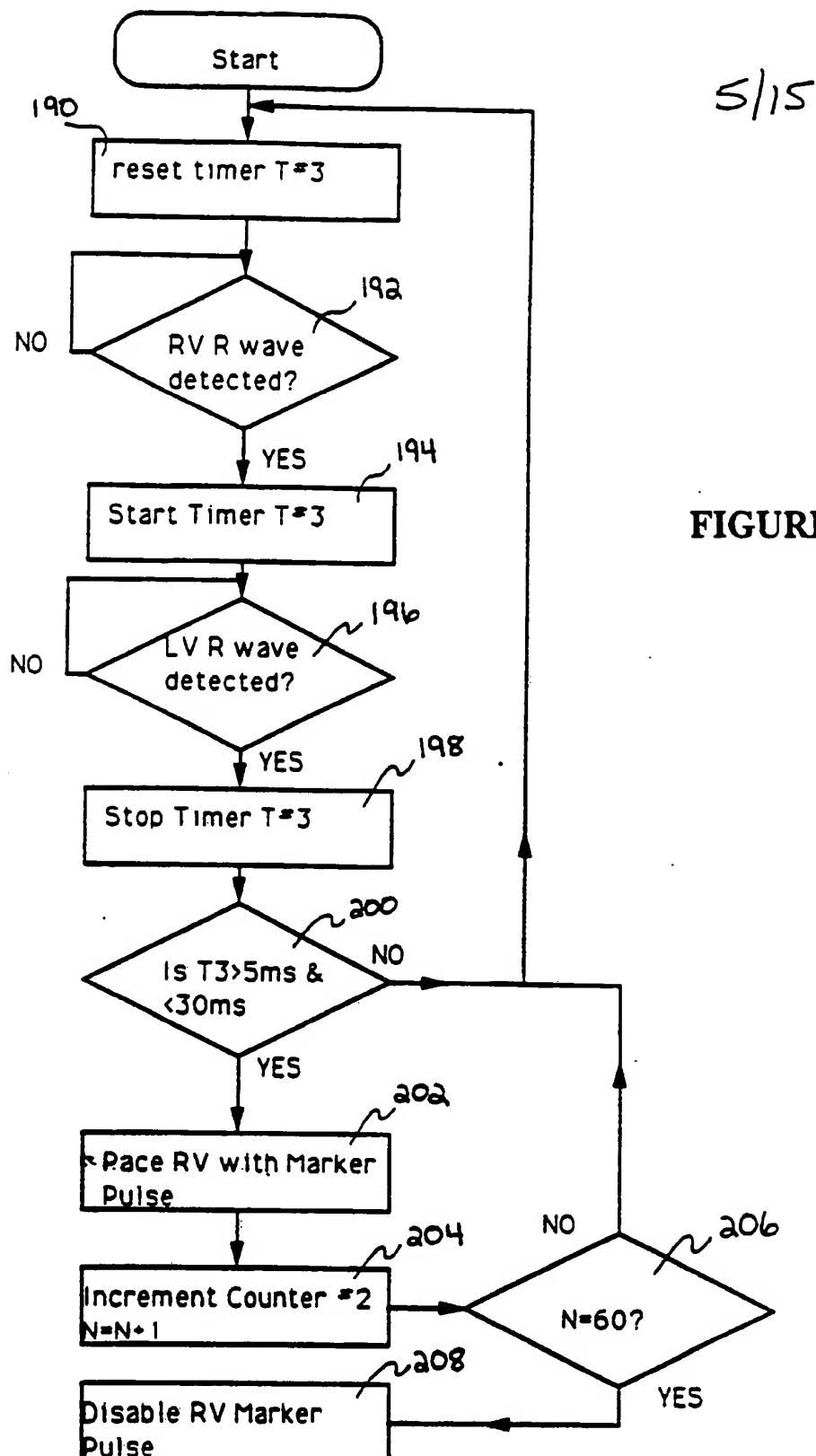
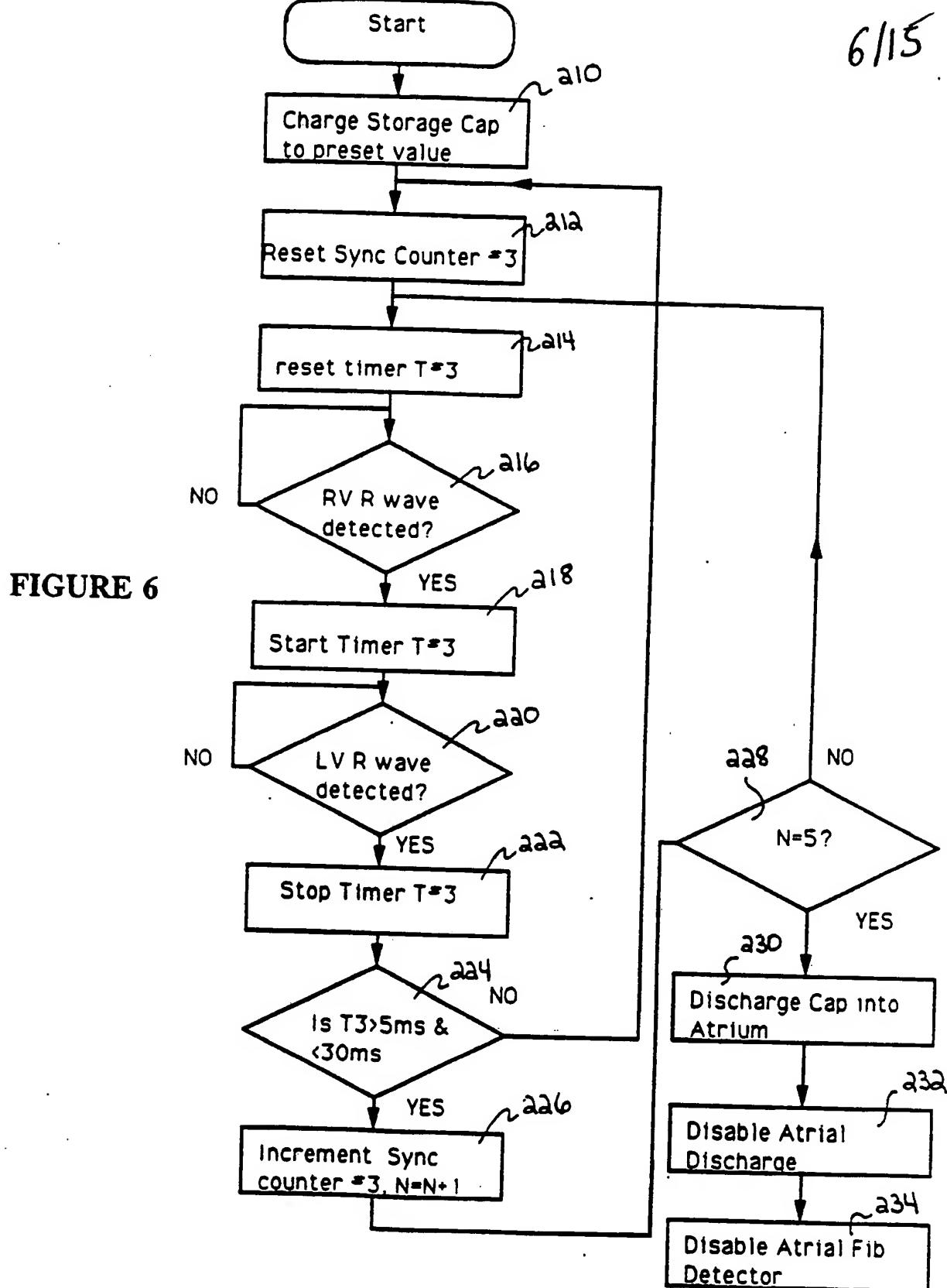
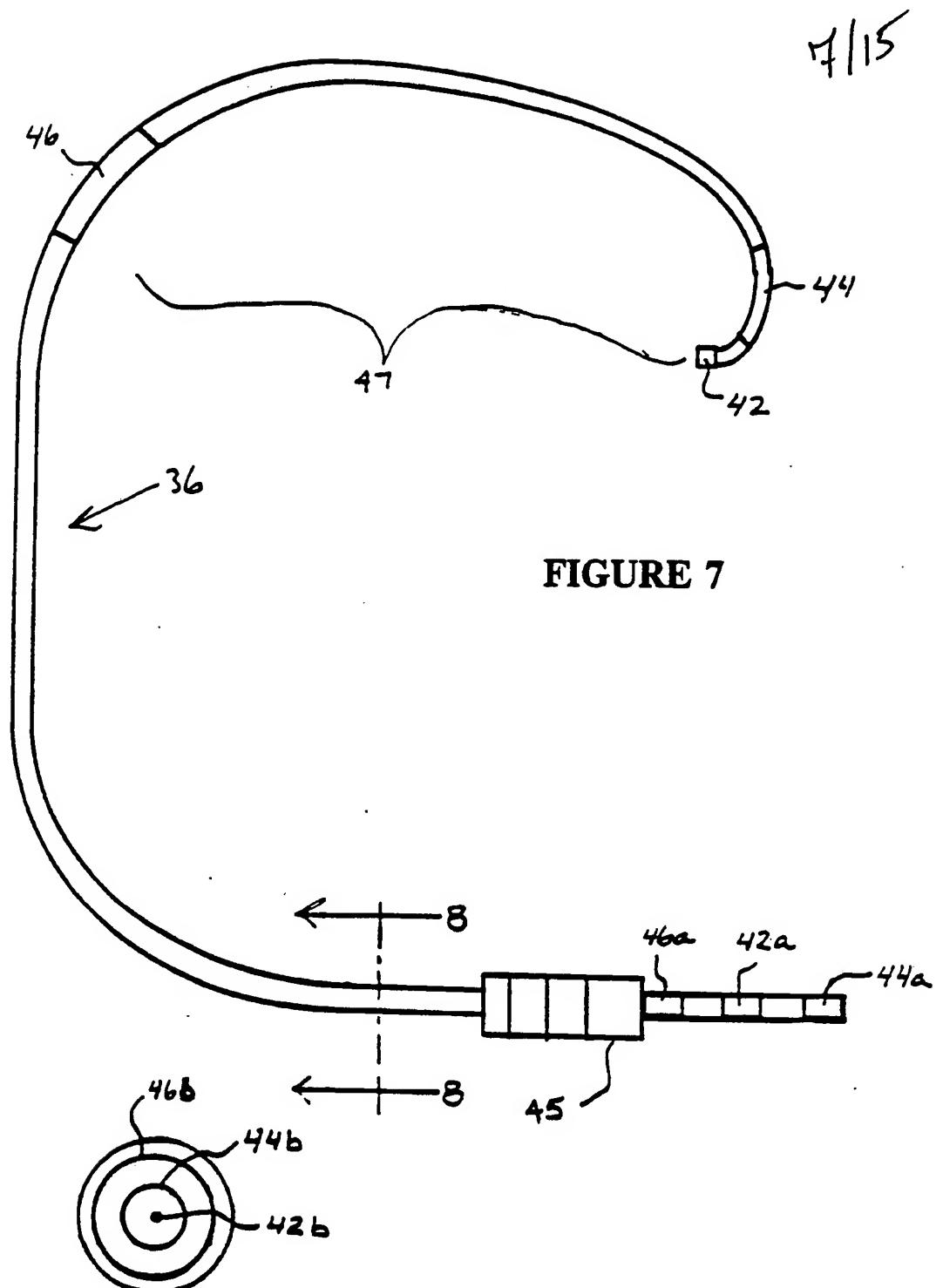
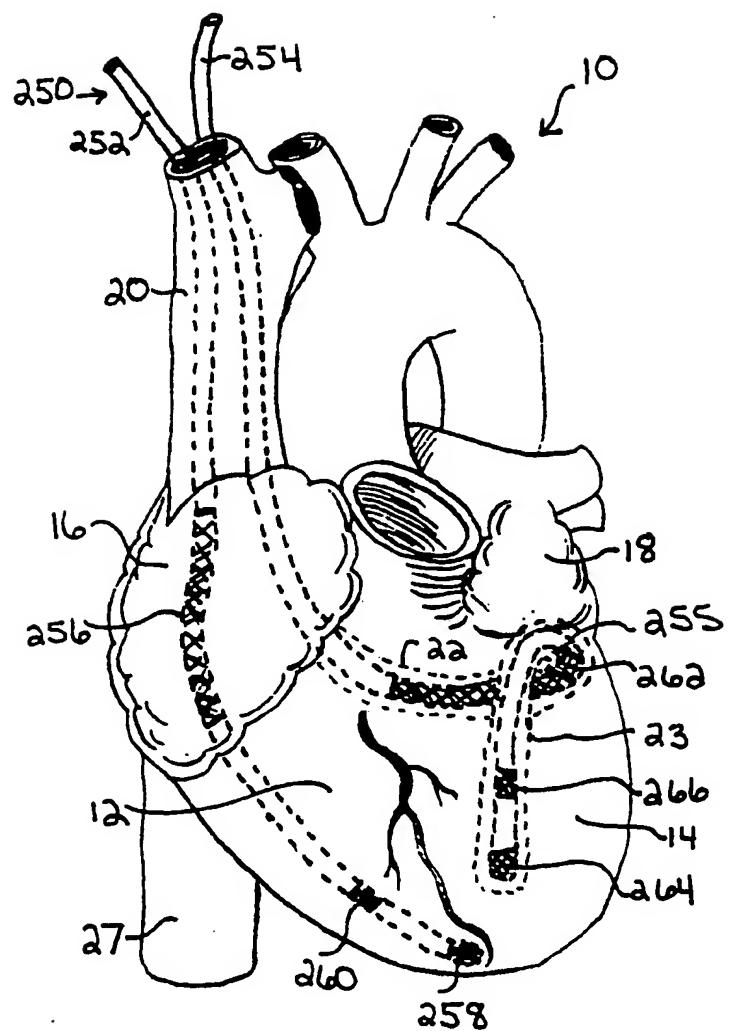


FIGURE 5



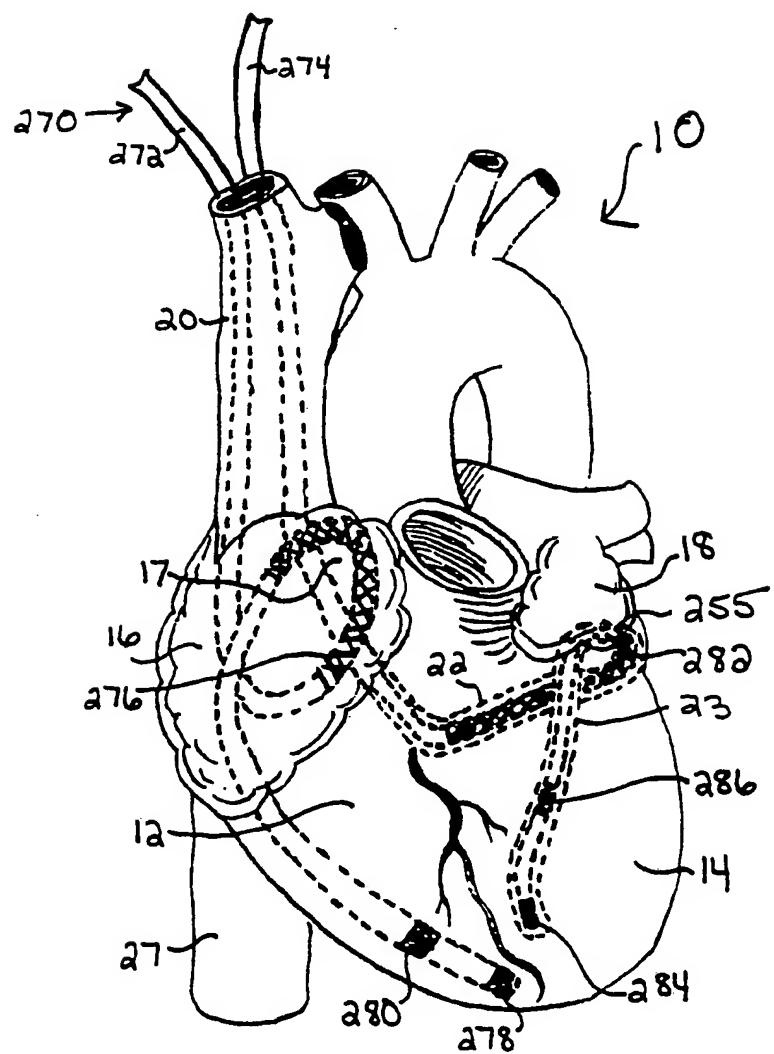


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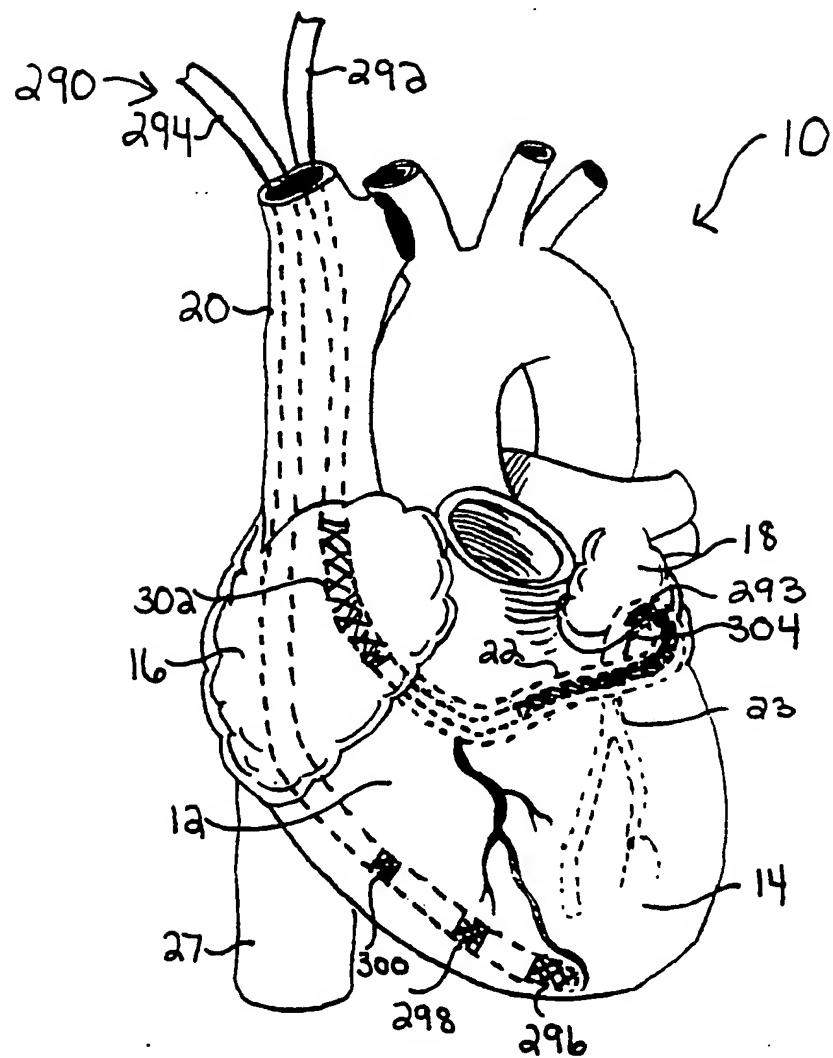


**FIGURE 9**

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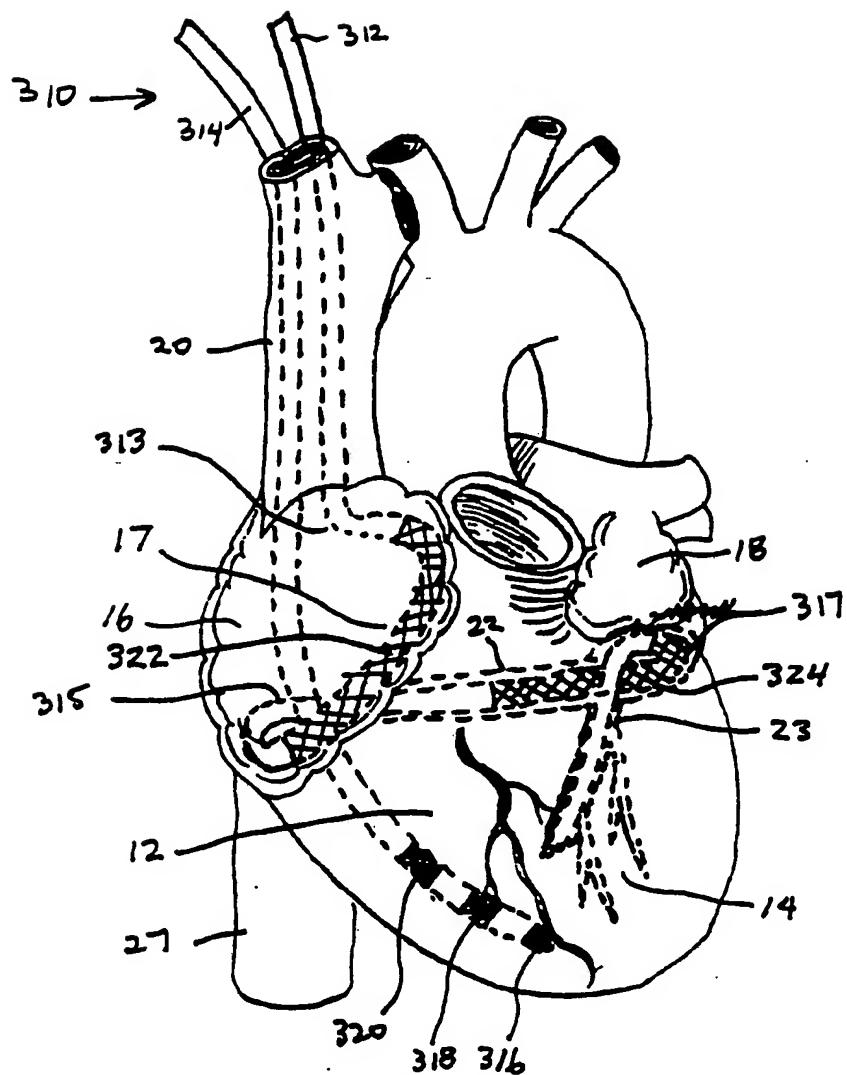
**FIGURE 10**

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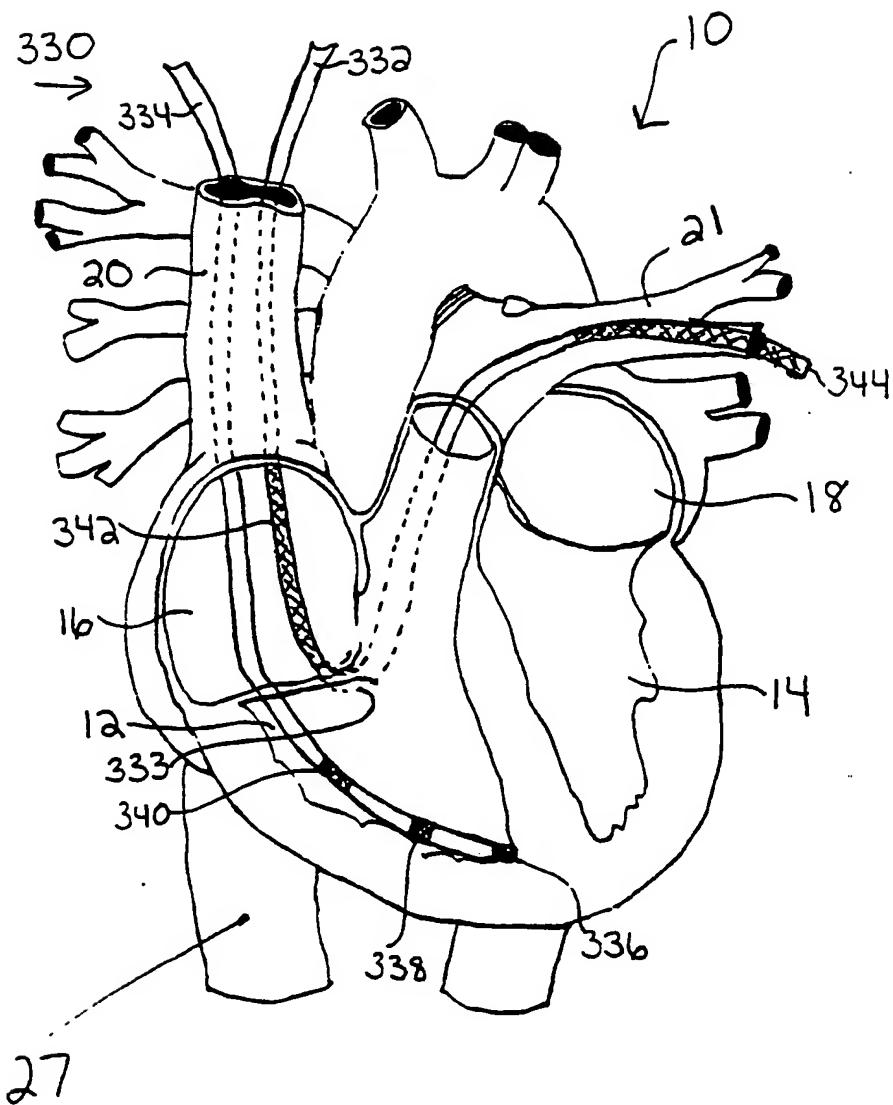


**FIGURE 11**

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**FIGURE 12**

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**FIGURE 13**

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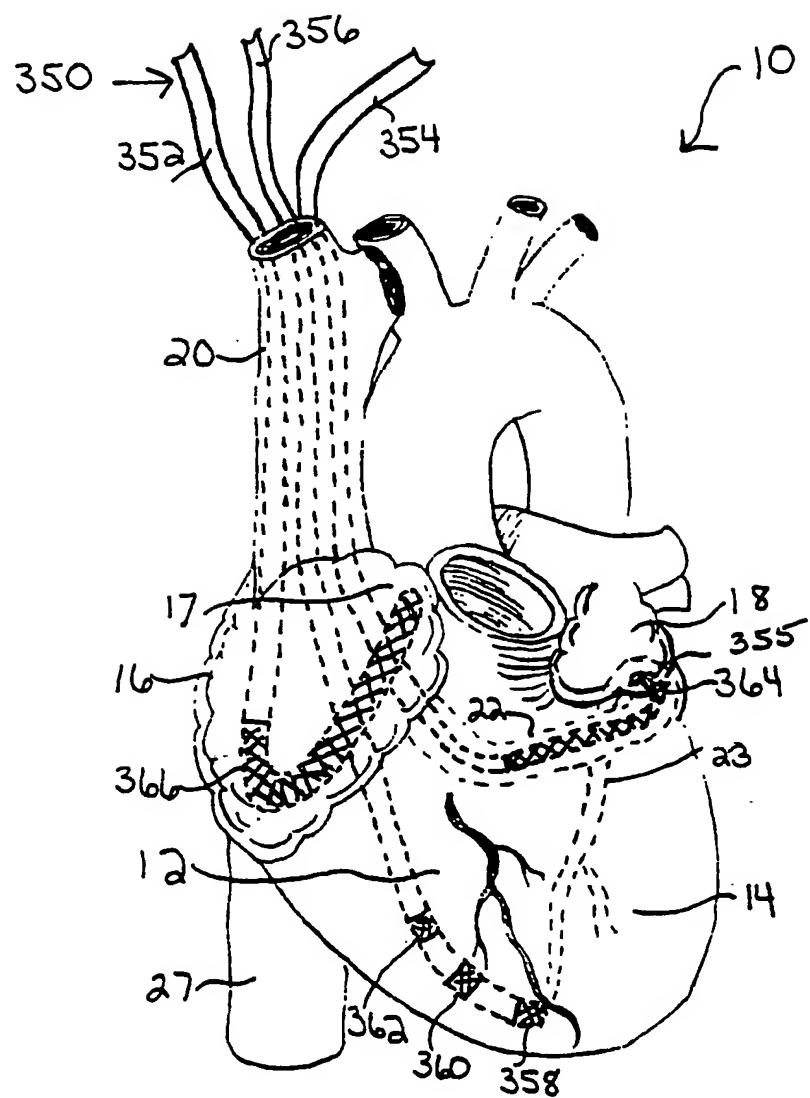
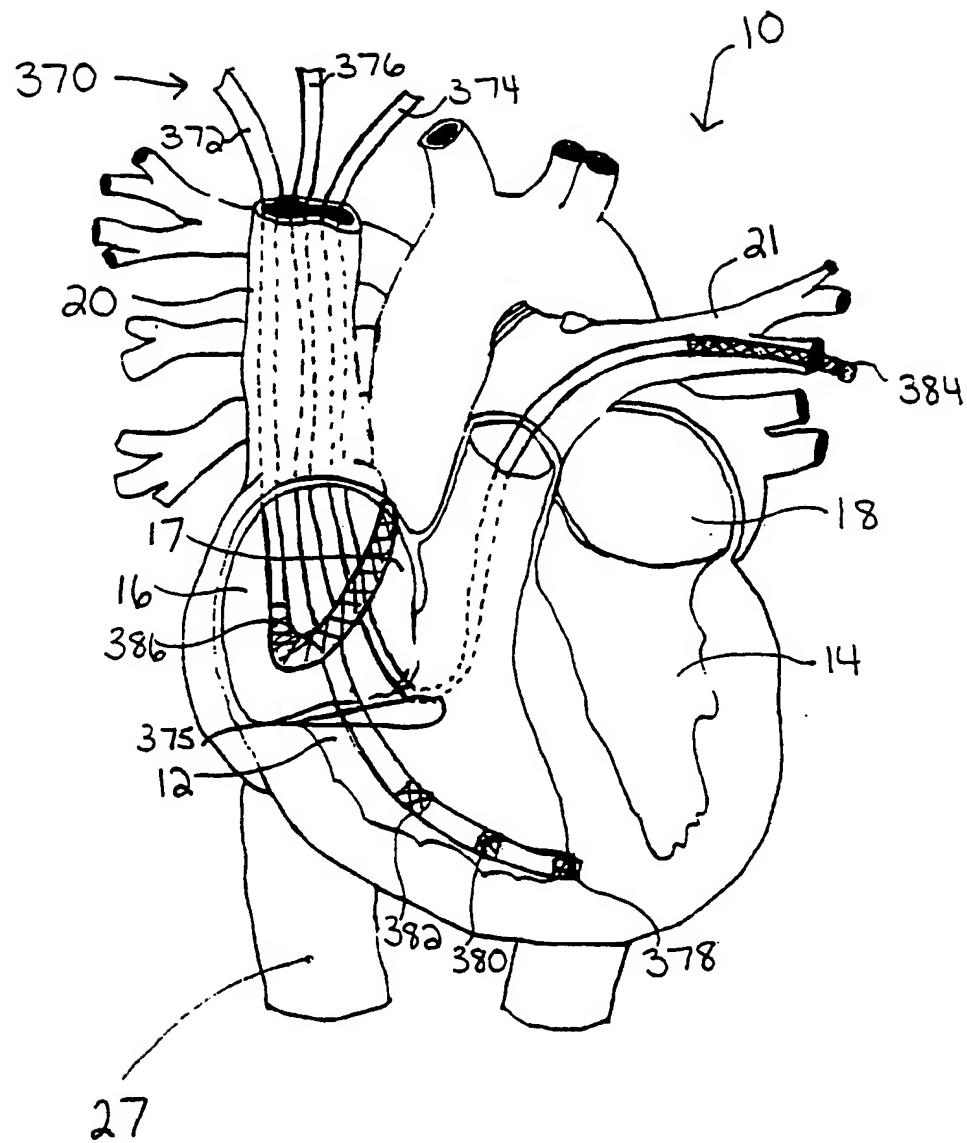


FIGURE 14

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S.G. 3-20-92  
C.R. 3-20-92

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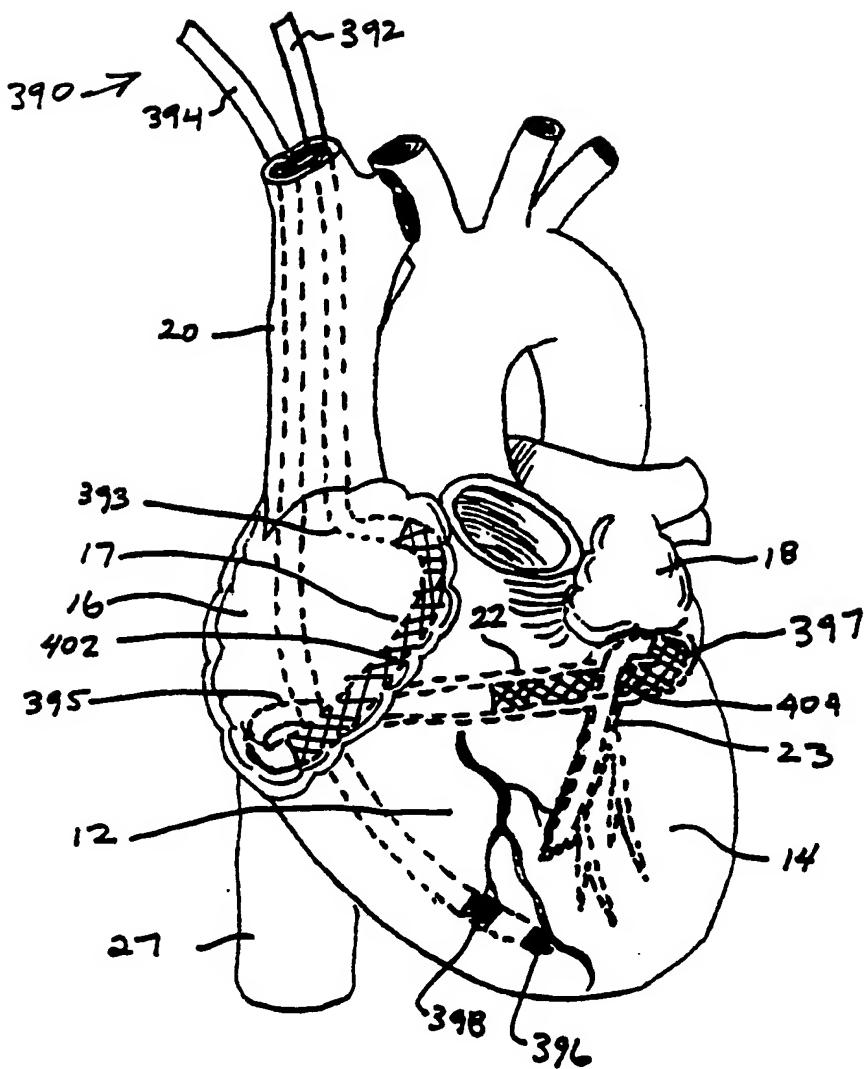


FIGURE 16